S. HRG. 99-834

RADIATION REORGANIZATION ACT OF 1985

HEARING

BEFORE THE

SUBCOMMITTEE ON
ENERGY, NUCLEAR PROLIFERATION, AND
GOVERNMENT PROCESSES

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

S. 525

TO TRANSFER TO THE SECRETARY OF HEALTH AND HUMAN SERVICES THE AUTHORITY OF THE SECRETARY OF ENERGY TO CONDUCT EPIDEMIOLOGICAL STUDIES OF THE EFFECTS OF RADIATION AND FOR OTHER PURPOSES

JUNE 17, 1986

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TUESDAY, JUNE 17, 1986

U.S. SENATE,
SUBCOMMITTEE ON ENERGY, NUCLEAR
PROLIFERATION, AND GOVERNMENT PROCESSES,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The subcommittee met at 10:06 in room SD-342, Dirksen Senate Office Building, Hon. Thad Cochran (chairman of the subcommittee) presiding.

Present: Senator Cochran and Senator Glenn.

OPENING STATEMENT OF SENATOR COCHRAN

Senator COCHRAN. The subcommittee will please come to order. This morning, we are conducting a hearing of the Subcommittee on Energy, Nuclear Proliferation and Government Processes of the Committee on Governmental Affairs on S. 525, the Radiation Reorganization Act of 1985. This is a bill that has been introduced by the distinguished Democratic ranking member, Senator Glenn, of this subcommittee, and the hearing is being held at his request.

The bill proposes to transfer the authority of the Secretary of Energy to conduct epidemiological studies on the health effects of low-level radiation to the Secretary of Health and Human Services.

We have three panels of witnesses who will testify this morning. First will be a group who support the bill; the second panel will consist of administration and Department of Energy witnesses to discuss the work that is being done and whether or not the administration supports this transfer; and the third panel will consist of experts who have reviewed the studies and how they are being done to discuss their views of the legislation.

We want to welcome all witnesses. We appreciate your participation in being here today and for providing advanced copies of your statements.

Senator Glenn.

OPENING STATEMENT OF SENATOR GLENN

Senator GLENN. Thank you, Mr. Chairman, and I want to thank you very much for holding this hearing on S. 525, the Radiation Reorganization Act. I would like to provide just a little bit of background in order to place the bill in proper context.

Mr. Chairman, about 8 years ago, the Secretary of HEW established the Interagency Task Force on the Health Effects of Ionizing Radiation to address the question of overlapping and fragmented

jurisdiction by Federal agencies in both radiation protection and in radiation research.

Among the items specifically considered by the task force was a study of ways of expanding the role of health and regulatory agencies in the area of radiation in order to dispel some of the public perception of: "a conflict between DOE's role as the primary sponsor of research into the biological effects of ionizing radiation and its roles as a developer and promoter of nuclear energy, and, as an employer, through contractors of workers exposed to radiation during the production of nuclear weapons."

The task force review resulted in recommendations that:

> A review be made of existing programs and the proposed research agenda in this area to determine whether it is appropriate to transfer portions of DOE's research budget to other agencies and, if it is appropriate, recommend which projects to transfer.

Former HEW Secretary Joseph Califano, in the last memorandum he sent to President Carter before leaving office, dealt very specifically with the question of agency research roles. He wrote:

> My recommendation goes beyond the task force's on this issue. I feel strongly that the major responsibility for research into the health effects of low-level radiation should be placed in an agency which has health-related research as its primary responsibility. The credibility of government supported research in this area will be compromised if the major source of funding continues to be the agency responsible for developing nuclear weapons and developing and promoting energy sources that result in radiation exposure.
>
> The inherently schizophrenic nature of this dual mission has already damaged the credibility of the Government's efforts to protect the public health; indeed, there are responsible scientists who believe that it has damaged the public health itself.
>
> I believe that the balance of resources should be shifted from DOE to NIH and other health-related agencies over the next 2 or 3 fiscal years. * * *
>
> I believe that research funding could be shifted without losing valuable scientific expertise.

Mr. Chairman, I introduced legislation in the 96th and 97th Congresses to establish coordinating groups on radiation policy, radiation effects, and radiation research that, in my view, would have expedited the process of setting standards for protection of the public as well as providing the basis for radiation research untainted by any charges, whether founded or not, of conflict of interest.

As it turned out, neither President Carter nor President Reagan were interested in a legislated solution to this problem. Both chose to deal with it by means of setting up coordinating bodies by Executive order. President Carter's efforts in this area were vitiated by President Reagan when he took office in 1981, but then President Reagan turned around shortly afterward and established the Radiation Policy Coordination Committee, which operates within the White House's Office of Science and Technology Policy.

Among the questions which my legislation would have addressed at the time was precisely the one addressed by secretary Califano in his memo to President Carter. This problem, unfortunately, has not gone away, and is being addressed only on a piecemeal basis, if at all. It is true that DOE's share of research on radiation protection has declined in recent years, but DOE still funds about 60 percent of the radiation health studies that are performed.

DOE's own studies on the cancer risks of protracted exposure to low doses of ionizing radiation have turned up some evidence that

workers at a number of their plants do suffer from excess mortality and morbidity as compared to comparable control population.

Let me give a few examples: Workers at the Oak Ridge National Laboratory have a 49-percent increased risk of leukemia compared to the general public.

Workers at Oak Ridge's Y12 weapons plant had excess depths from cancer of the lung, brain, and central nervous system, as well as from Hodgkin's Disease.

Workers at DOE's Fernald, OH, uranium processing plant have elevated risks of death from digestive cancers and exhibit an association between exposure to uranium and development of nonmalignant respiratory disease.

Excess cases of leukemia have been found in the employees of the Savannah River plant.

While these findings may not, at this time, be definitive, some of the studies have been marked by controversy associated with purported attempts by DOE or its contractors to lessen the impact of unfavorable results. In one case, at least, DOE removed the principal investigator of the study and replaced him by DOE's own scientists.

It is not my intention either in this statement or in the legislation to impugn the integrity of the Department of Energy or the scientists who work for DOE, but when we are dealing with the question of the scientific basis for findings and regulations regarding public health and safety, we cannot afford to allow even the appearance of conflict of interest.

Otherwise, we raise serious questions in the public's mind about whether radiation protection programs and research are being objectively pursued with the public interest foremost.

And so, Mr. Chairman, I introduced S. 525 to transfer to the Secretary of Health and Human Services the authority of the Secretary of Energy to conduct epidemiological studies of the effects of radiation. This proposal is in keeping with the conclusions of the Interagency Task Force on the Health Effects of Ionizing Radiation in 1979 and also with the legislation I had introduced in 1980 and 1982.

Mr. Chairman, I thank you, again, for holding this hearing, and I, too, want to welcome our witnesses today.

Thank you.

Senator COCHRAN. Our first panel of witnesses includes: Robert Alvarez of the Environmental Policy Institute, Washington, DC; Dr. Carl Johnson, medical officer of the South Dakota Department of Health, and Thurman Wenzel of International Chemical Workers Union of Akron, OH.

If you three gentlemen would come forward and take your places, we have the statements which you have prepared for the hearing. Again, let me thank you for that. We will include each statement in the record in its entirety and encourage you to make such summary comments or highlights from those statements as you care to make. That will leave the subcommittee with an opportunity for some discussion of the issues that you raise. Let's begin with Robert Alvarez.

TESTIMONY OF ROBERT ALVAREZ, ENVIRONMENTAL POLICY INSTITUTE, WASHINGTON, DC.;[1] CARL JOHNSON, M.D., MEDICAL OFFICER, SOUTH DAKOTA DEPARTMENT OF HEALTH;[2] AND THURMAN WENZL, INTERNATIONAL CHEMICAL WORKERS UNION, AKRON, OH[3]

Mr. ALVAREZ. Thank you. Good morning. I would like to thank Senator Cochran and Senator Glenn for inviting me to present my views relative to this important legislation. For the record, my name is Robert Alvarez. I am director of the nuclear power and weapons project at the Environmental Policy Institute, a position I have held since 1975.

The Environmental Policy Institute is a nonprofit public interest research and advocacy organization.

The Environmental Policy Institute strongly supports enactment of S. 525, legislation which would transfer authority to conduct radiation and epidemiological research from the Department of Energy to the Department of Health and Human Services. There are several compelling reasons why this legislation is necessary.

First, the control exercised by DOE over this sensitive area of research has compromised scientific objectivity to the point where American citizens no longer trust Federal agencies to protect them from civilian and military nuclear activities. The source of this mistrust is a legitimate concern of the health of thousands of people who live near or work in nuclear facilities may be in jeopardy. DOE's interest in radiation health effects stems from their primary missions to produce nuclear weapons and promote nuclear energy. This fundamental conflict of interest between nuclear promotion and public health protection has been well documented for the past several years by extensive congressional oversight hearings, Federal court decisions and executive agency investigations.

Second, for more than 40 years, hundreds of thousands of military and civilian personnel and people living near military installations have been exposed to levels of ionizing radiation from nuclear weapons developed which are shown to be dangerous.

For example, at the end of February of this year, after a significant amount of pressure over a period of many years, the Department of Energy was compelled to release over 19,000 pages of mainly documents that were classified prior to that time detailing the operating history of the Hanford facility in Washington State. As you may know, Hanford is the world's oldest nuclear installation and the nation's largest nuclear waste and toxic storage site.

It was revealed that in one year alone, 1949, the Energy Department deliberately released 5,500 curies of radioiodine. They did it, not because they were interested in producing plutonium, but they wanted to see where this cloud would land. The exact reasons why this experiment was conducted still remain a military secret.

I may point out that this was about 460 times larger than the amount officially admitted to have leaked from the Three Mile Island II accident in 1979.

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[1] Mr. Alvarez' prepared statement appears on p. 48.
[2] Dr. Johnson's prepared statement, with attachments, appears on p. 69.
[3] Mr. Wenzl's prepared statement, with attachments, appears on p. 104.

Moreover, in 1945, the year that Hanford was producing the first plutonium for the Nagasaki bomb, approximately 375,000 curies of radioiodine were deliberately released in the environment, which is about 25,000 times larger than the Three Mile Island official estimate.

The public living near by these facilities were never informed of these events. They had extensive leaks that went on all the way through the 1960's. For example, there were as many as eight Chernobyl-type reactors operating at Hanford that would withdraw water from the Columbia River, run it through the core of the reactor's coolant; return the water to an extremely contaminated form back to the river. A few miles downstream, the farmers would take water out of the steam and grown and eat contaminated food, and their families would swim in the water. Yet they never knew about it. The farmers who lived near this facility refer to this stretch of land as "death mile." Only 1 out of 10 farms have escaped cancer.

I had the pleasure of participating in a meeting in Spokane, WA about the Hanford facility where a farmer was uninvited, crashed the meeting, and, I think, gave a very eloquent statement which I think characterized the dynamics of this conflict of interest. The gist of what he said is this: This was about 3 days after the Chernobyl accident. He said that:

> The nations of the world have condemned Russia for 3 days of silence. Is there a crime no worse that has been done to us, and is their silence of 3 days worse than Hanford's silence of 40 years?

Having DOE control research which will determine the outcome of not only radiation protection standards but also compensation claims, to me, is a clear violation of basic principles of scientific freedom and responsibilities.

Third, DOE's installed industrial capacity to manufacturer nuclear weapons is in excess of 30 years of age. Athough changes in nuclear health and safety standards relative to commercial nuclear power plants have undergone steady change, DOE's standards for facilities have not changed significantly for more than 25 years.

For example, if you were to live near a Department of Energy nuclear facility as a member of the public, you are allowed to live near 20 times more radiation annually than if you were living near a commercial reactor. Thus, studies which suggest that DOE's nuclear facilities pose unacceptable health risks to workers and to members of the public are perceived to DOE as threats to their primary mission. In essence, DOE's bureaucratic self-interest has dangerously blurred distinctions between national security and protecting the health of American citizens from nuclear facilities.

In a candid but disturbing comment on the priorities of DOE, Dr. William Loewe, a radiation health effects expert at DOE's Livermore National Laboratory, stated resently, "There are tens of billios of dollars to be spent in the commercial and nuclear defense industries if protection standards were to be changed." Loewe successfully characterized the kind of pressure that compromises objective research funded and supervised by the Energy Department.

DOE's control over radiation epidemiologic studies reflects an inherent bais which has taken the forms of misleading statistics and

crude analytical methods which are then used to support spurious claims about the lack of health risks at DOE installations.

For example, in 1984, an official publication in the Oak Ridge National Lab called "Review" made note of the fact that it was safer to work at the lab than to stay at home. This was an editorial that was made in regard to the health studies that were being done of workers at Oak Ridge when, in fact, the study showed two things: It showed an increase risk of dying of leukemia of certain job categories for an increase risk. One study that has yet to be published suggests that for those hired later than 1949 and under 39 at the date of hire and exposed to radiation, your risk of dying from all cancers is about nine times greater than the unexposed workers. Yet DOE, through the national lab, only informed workers that it was safer to work at the lab than stay at home.

DOE officials have publicly attacked independent scientists, while internally acknowledging that the same methods used by these scientists are superior.

At the heart of DOE's conflict of interest is its policy on epidemiologic utilization of data. Researchers analyzing DOE worker data are not allowed direct access to source data and are therefore not in a position to verify the data's accuracy and completeness. They are also not in a position to prevent the destruction of records which may prove valuable for research but also may be damaging to DOE's efforts to fend off compensation claims.

Officials at DOE's Oak Ridge Associated Universities, which is a Government-owned contract-operated facility that holds a major contract to conduct his research, confirmed last November that they did share the burn 21 out of 41 filing cabinets of medical records of Oak Ridge residents which were set aside by the original principal investigator in DOE's occupational health and mortality studies.

Moreover, DOE and Oak Ridge Associated Universities were aware that these records were listed in an iventory of data by the original principal investigator as source data. Whether or not these records were destroyed deliberately or out of carelessness does not change the damage done relative to epidemiological studies of Oak Ridge people and the ability of residents of Oak Ridge to obtain compensation.

Although DOE claims that their data utilization policy is designed to comply with the Privacy Act, such restrictions are not placed on investigators of public health agencies like the National Institutes of Occupational Safety and Health. The Subcommittee on Energy, Nuclear Proliferation and Government Processes should ask the General Accounting Office to investigate the extent to which data in the possession of DOE or its contractors has been destroyed or is being properly assembled.

Removal of the DOE from the funding and supervision of epidemiologic research is necessary for the development of objective radiation protection policies. This step is vital if the Federal nuclear program is to meet the same health and safe standards as those required by the private nuclear program. Not only will this legislation help restore credibility of the Federal Government in protecting its citizens from nuclear activities, it would perform a service for both sides of the radiation health effects debate.

This concludes my statement. Thank you very much.

Senator COCHRAN. Thank you, Mr. Alvarez.

Our next witness is Dr. Carl Johnson.

Dr. JOHNSON. Thank you for the opportunity to testify concerning this bill. This bill will result in more effective administration of research programs dealing with the study of radiation effects. Each Department has a mission; it is important to assign work consistent with the mission of that Department. It is counterproductive to assign responsibilities to a Department which are in conflict with its mission.

The principal DOE mission is to produce nuclear weapons and nuclear materials. This involves working with very hazardous materials known to cause injury. Further, these materials are released offsite from DOE's facilities and present a hazard to the public. Rocky Flats, Savannah River and Hanford plants and the Nevada test site are examples. Many workers are suing DOE corporate contractors and the DOE, claiming injury from these materials and their radiation. Local people have charged injury by radioactive materials released offsite. Landowners claim their land is unsafe for housing due to contamination by a DOE facility. Plaintiffs in these lawsuits seek key information from epidemiologic studies supported by the defendant DOE—studies of radiation effects such as cancer.

Their suits are more difficult because of lack of reliable information concerning such effects, and because delayed effects of radiation are more important than immediate effects. To assign the studies of the health impact of DOE activities to the DOE itself creates a blatant conflict of interest situation.

This conflict of interest is not at all subtle; it is easily seen by the public. The fact that some of the DOE national laboratories develop nuclear weapons and some also do health studies does not lead the public to believe that these health studies are independent. Some believe the so-called "peer review" system is nothing more than an old-boy network.

Please see the attached affidavits describing one case history.[1]

The Department of Health and Human Services has the mission to protect and promote the health of workers and the public. It makes much better administrative sense to assign these investigations of injury and disease caused by radiation to this Department, despite the protests of losing and receiving departments and their sister agencies.

While DOE strongly opposes this bill, they offer little support for this position. The AEC and the DOE record on the health of workers and the public exposed to radioactive materials is well documented in court proceedings and in congressional testimony. Recent citations appear in "Justice Downwind", written by a college dean at the University of Utah. Downwind of the test site, radiation instruments went off the scale in the city streets, and official records were later falsified to indicate low readings.

Deaths of thousands of sheep in the path of nuclear clouds were dismissed as "malnutrition" by federally supported scientists in the

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[1] See p. 84.

early court case. Public Health Service agents burned their clothes and showered to decontaminate themselves, but under AEC orders reassured local people that no precautions were needed. Children played outside during periods of peak fallout, and pregnant women worked in their gardens. Families ate their produce, milk, and meat contaminated with fallout radionuclides, with little early evidence of the insidious injuries being sustained.

AEC used Public Health Service and media professionals and consultant professors to convince the trusting public that there was no hazard, no need for even the simplest measures to protect themselves against nuclear fallout.

Early health effects could not be reported, because, according to a Deputy Director of the Atomic Energy Commission, "we can't change our story now; we'll be in trouble." A few scientists who objected were told by a former Chair of the Joint Committee on Atomic Energy, "Listen, there have been a lot of guys like you who tried interfere with AEC programs; we got them and we'll get you."

Instances of deception and intimidation of concerned scientists are not part of the public record. These practices are continued today by the Department of Energy. Where are the studies of population effects around nuclear facilities? The nuclear establishment, like the tobacco, chemical, and asbestos industries, has resisted objective, aggressive efforts to study the effects of its radioactive releases on human health. An example is an AEC internal memo to AEC Commissioner Haworth and other AEC commissioners. In studying the health effects of fallout:

> Start with a simple, straightforward statement of conclusions. We would then identify the major questions that could be expected to be asked in connection with these conclusions. It would then be a straightforward matter to select key scientific consultants whose opinions should be sought in order to substantiate the validity of the conclusions and recommend appropriate modifications.

The key scientific consultants include their own scientists and university professors willing to serve as consultants and who support agency doctrine. These key scientific consultants are the respected scientists from noted universities and research institutes the so-called scientific peers, who review manuscripts and grant applications dealing with the studies of radiation effects.

Despite this Orwellian version of the scientific method, few studies have actually been done of the efects of fallout or the effects of radiation on nuclear plant workers.

Even fewer studies have been done of the effects of radioactive exhaust plumes and contaminated water released from nuclear installations.

Research sponsored by the AEC/DOE has been self-serving to the nuclear industry.

For example, the consistent minimization of the actual toxicity of nuclear materials; studies of cancer deaths rather than cancer incidence in plutonium workers and other exposed populations and comparing the highly selected nuclear workers to the general population. The trivialization of exposure to uranium; the nonprotective permissible limits for tritium in water; the standards of permissible body burdens of plutonium and similar transuranics for the public and for nuclear workers which permit chromosome damage.

Using the official but non-protective DOE guidelines for nuclear workers, you can calculate that 1 cubic centimeter of plutonium-239 represents the permissible body burden of plutonium for 45 million nuclear workers or more than 4 billion people. One cubic centimeter of plutonium-238 would exceed these limits for 11 billion nuclear workers or 1 trillion people. As an indication of the extreme toxicities of these materials, we can contrast these tiny amounts, one-quarter teaspoon, with many tons of plutonium produced by DOE and other reactors that operate without containment at Hanford, and at other nuclear plants. These extremely toxic reactor wastes must be stored in perpetuity, but may also be reprocessed to manufacture nuclear weapons, increasing the risk of environmental pollution.

We have not developed sufficient information about the potential for health effects of these materials from DOE research. Individual research has been discouraged because of lack of funding and lack of basic information concerning actual worker exposures and actual releases from nuclear plants and nuclear installations. In 1978, DOE spokesmen alleged that plutonium levels in the air near the Rocky Flats were near that from background. In fact, another DOE branch has measured plutonium levels in the air near the Rocky Flats were near that from background. In fact, another DOE branch has measured plutonium levels around Rocky Flats for a number of years as part of their plutonium network, and for every month measured, the Rocky Flats area had the highest level reported in the world.

The DOE has relied on the so-called BEIR-1980 Report. The most recent citation in this was published in 1979. Today, more than 20,000 scientific reports on cancer causation have been published since 1979, but have not been cited by the BEIR committee.

Where are the published reports of DOE research over the past 40 years in major journals on the effects on population from fallout or from off-site contamination around nuclear plants, or of effects on workers? Should we believe there are no effects?

The national laboratory scientists and the university professors get large sums of money to do research for an agency which is quite protective of its interests. The scientist and professor will take care not to jeopardize the annual renewing of their research funds.

I cite the case of Dr. Edward Rack, Professor at the University of Nebraska, whose research is supported by the DOE and who is "an expert involving radioactivity." Professor Rack agreed to provide expert testimony in an action by a Rocky Flats worker claiming injury due to plutonium deposits in his body. I have attached depositions and a letter indicating that Professor Rack was intimidated by a threat of losing his DOE grants, causing him to withdraw as consultant expert witness from this case.[1] The key scientist of the national laboratory is in a similar situation.

The national laboratories not only do health studies, they develop nuclear weapons and do related research. The priority of these laboratories is to serve the overriding mission of DOE, which is not

[1] The depositions and the letter referred to follow Dr. Johnson's prepared statement which begins on p. 69.

to protect the health of the worker and the public, but to create nuclear weapons and materials. I believe the record of the national laboratories in this area is very poor. These research funds should be diverted to new, independent and aggressive research scientists who operate outside of this particular system.

The DOE invokes an air of great mystique around nuclear technology and studies of cancer and refers to the analysis of extremely complex data in these studies. This is a dodge used over the past 40 years with considerable success. In fact, such studies need not be difficult. As an example, the EPA speaks of radionuclides in picocuries per gram of soil, picocuries per liter of water, and picocuries per cubic meter of air.

In contrast, DOE uses an odd and awkward physicist's pig latin, discussing contamination in terms of 10 to the power of minus 12 microcuries per milliliter. Their own personnel can scarcely manage this terminology, and I have seen their scientists become quite confused in dealing with these terms. I cite this only as an example of efforts to make radiation matters obscure and remote to the public.

The DOE and NRC studies, in my opinion, have not been well-designed in many cases. They rely often on studies of cancer deaths, a poor measure of effect on populations. The more sensitive and stronger cancer incidence studies have usually been neglected, and there are few such studies which have been published in major journals by DOE-supported researchers or national laboratories.

The DOE acknowledges this conflict between their principal task and their role as advocate for the health and welfare of their employees. They fail to note also their need to protect the DOE and its contractors from suits by injured employees and the public. DOE really has no good argument against the transfer of authority to conduct these studies. I am convinced that this administrative action would result in more effective use of public tax dollars and for less money, we will have radiation studies of higher quality and reliability and with greater objectivity.

The NRC general counsel endorsed the transfer of radiation epidemiology research programs, and so would support this bill. Commissioner Asselstine believes that the public health-oriented agencies, such as NIH, are best suited to have primary responsibility for radiation effects research, including epidemiology studies, and he would prefer this reorganization.

Other members of the Commission see little benefit in this bill, but their objections are poorly supported. They have their own conflict of interest situation as a sister agency which also funds studies of radiation effects on the health. NRC supports the interests of nuclear power and cannot be objective concerning issues over the health effects of radiation, and neither are the NRC contractors, in my opinion.

EPA opposes this bill, and this position reflects the input from the Office of Radiation Programs, which has been staffed by former members of the Atomic Energy Commission. It is not surprising that they would show loyalty to the AEC and the nuclear industry from which they may later seek employment.

An example of their lack of objectivity is the specific exception of uranium regulations from the EPA drinking water regulations of

1977, and their own controversial guidelines for plutonium and other transuranics in soil of 1978, which were never signed into law by either President Carter or President Reagan.

The EPA opposes this bill because it could result in a less clear focus for the epidemiology program and a lack of coordination. This interesting statement shows that DOE studies are not independent.

The science adviser to the President does not support this bill, but provides no substantive support for his position. The adviser does not question the credibility of DHHS nor its ability to do an excellent job. He notes that epidemiologic studies by DOE are interwoven into and supported by the national laboratory system, with all its staff and contract programs. This also speaks to a lack of independence in such studies.

The adviser depends on two NAS studies on this question, a needless waste of public funds to belabor a decision that should have been purely administrative. Those studies actually found that DOE had need for an increased use of a formal peer review process, increased publication of study results and increased interagency communication. While the adviser states there seems to be numerous arguments against passage of this bill, he does not cite a single argument.

Former Secretary Heckler simply defers to the science adviser. She denies evidence for claims of conflict of interest, but provides no assurance that she has really looked for any. She suggests an outside scientific advisory body presumably of key scientific consultants, but again avoids the simple administrative wisdom of this bill.

In summary, under the leadership of the AEC and the DOE, research has not proceeded in an adequate manner into the health effects from nuclear bomb tests; the manufacture of nuclear weapons; living near nuclear production facilities, nuclear powerplants and radioactive wastes; and into the medical uses of radioactive materials.

There is an important purpose for basic research and epidemiological investigations. This is to provide a foundation for meaningful and protective public health rules and regulations and concentration limits, which must then be enforced. The effect of involving DOE in this research clearly asks the fox to monitor the henhouse. In defense of this, the DOE could argue that the fox is an expert on chickens. A better analogy: We have hired Willie Sutton to guard the bank. Willie Sutton was a notorious bank robber, and it could be argued that he was an expert on banks.

When the DOE sponsors research with results that do injury to its mission, there is strong motivation to suppress such information, or more likely, DOE avoids funding such research in the first place, or chooses key scientific consultants who can be relied upon not to produce damaging evidence. Dr. Karl Morgan, formerly Director of Health Physics at Oak Ridge, knows of examples of such DOE and AEC practices.

I think tax money has been squandered by relying on a nuclear weapons agency to do our health research. At a time when we are called upon to economize on public expenditures, it makes good business sense to use these health research funds more effectively by granting these funds to the agency whose business or primary

mission is the protection of public health and the health of the worker. It is simply a matter of good administrative practice, as I reported to the Interagency Task Force on the Health Effects of Radiation in 1979 at the Denver meeting.

More importantly, a strong case can be made that the public's health has been compromised. Despite the expenditure of hundreds of millions or perhaps billions of tax dollars over the past 40 years, there is still a distressing lack of information about the relationship between exposure to radioactive materials and health effects in plants animals and man. I urge that this legislation be supported.

I thank the subcommittee for allowing me to present this testimony. I did submit a number of earlier exhibits to support my testimony. I will be glad to discuss each exhibit.

I have an updated manuscript which I will leave with the clerk.

Senator COCHRAN. Thank you, Dr. Johnson.

Our next witness is Thurman Wenzl. You may proceed.

Mr. Wenzl. Thank you, Mr. Chairman. My name is Thurman Wenzl; I am an industrial hygienist at the Health and Safety Department of the International Chemical Workers Union in Akron, OH. I would first like to thank the Subcommittee on Energy, Nuclear Proliferation and Government Processes for giving us the opportunity to express our support for Senate bill 525 transferring of responsibilities for radiation epidemiology studies to the Department of Health and Human Services. Our support for this bill is based on our experience which has shown that DOE is either unwilling or unable to order its priorities in a way which protects the health of workers and communities close to its facilities.

International Chemical Workers Union represents workers at DOE facilities in Ohio and Tennessee; these include the Feed Material Production Center near Cincinnati and the X-10 and Y-12 plants at Oak Ridge, TN. At each of these plants, the ICWU is part of a multiunion Atomic Trades & Labor Council which bargains directly with the DOE contractor about wages and working conditions, including health and safety matters.

I am here speaking on behalf of both the Atomic Trades & Labor Councils, representing all the workers at the plants near Cincinnati and Oak Ridge. The International Chemical Workers Union has one of the largest health and safety departments in the labor movement. I am one of four industrial hygienists, and we also have three health educators. Our responsibilities include advising the 50,000 members of the union around the country on potential health hazards at work and what to do to minimize the risks.

In addition to conducting formal classes on health hazard evaluation, we conduct walkthrough tours, make recommendations, and investigate serious accidents.

During the past 2 years, my responsibilities have included accident investigation and evaluation of exposures to hazardous substances at the DOE Feed Materials Production Center in Fernald, OH outside Cincinnati. This DOE facility had been operated by a subsidiary of National Lead until last fall and is now being run by a Westinghouse subsidiary. It is primarily engaged in the production of uranium metal for reactors. I have visited this plant three times and requested detailed information on airborne hazards and

control strategies. There is worker concern at this plant about radioactive and nonradioactive hazards. These include, for example, acid mists, as well as airborne uranium. In each case, I have recieved only partical responses to my information requests, either because the exposure data I am seeking does not exist or cannot be located.

Our support for this legislation is based in part on the detailed investigation of health conditions which we have been carrying on at this DOE plant outside Cincinnati. DOE has shown that it cannot or will not adequately protect the workers there and, at the very least, responsibility for epidemiology studies should be placed in an independent agency such as the Department of Health and Human Services, which has expertise in the study of public health questions.

Because of the past record of DOE in failing to act to protect and inform workers and community people near these facilities in Ohio and Tennessee, there is now a great skepticism of any health report originating in DOE, especially those which suggest that there is little hazard. These doubts by the public and workers are not always correct, but they are well-founded in the sense that they are based on a confirmed history of inadequate information and inadequate protection of the workers in the community.

I am not arguing that every report coming from DOE is incorrect, but that because I have confirmed that past DOE behavior is unsatisfactory, as a result, the workers and public have good reason to be skeptical. The only way to improve public confidence in future health studies is to transfer responsibility to an agency independent of DOE influence.

I will now go on to elaborate on the details of past and current hazards at the Fernald, OH facility and the very inadequate control DOE has exercised over the contractors in health and safety matters. The DOE has had in place a mechanism to identify problems, but this process has apparently been toothless, since identified problems have remained uncorrected for years. This continuing pattern of inadequate attention to health and safety concerns is the basis for the public's lack of confidence in DOE.

DOE has a program of periodically sending staff persons from Oak Ridge to this Fernald, OH facility to conduct appraisals of the health physics and industrial hygiene practices of the contractor firms. Following my comprehensive tour of the Feed Materials Production Center in August 1985, I asked for and received several of these past appraisals. Some of the recommendations made by the DOE industrial hygienists were similar to the rcommendations which I made following my 1985 tour.

For example, 4 years earlier, in 1941, a DOE appraisal recommended that the industrial hygiene monitoring program be expanded to enable a true assessment to be made of various physical and chemical hazards other than airbone uranium.

Four years later, this has clearly not yet been done, since the DOE contractor was unable to respond adequately to my inquiring about acid mists in several areas of the plant. They claimed they had not had a large enough industrial hygiene staff to take care of this requirement. This inadequate staffing is another deficiency

noted by DOE 2 years earleir in their 1983 appraisal but still not addressed by the contractor in mid-1985.

While DOE has thus had in place a mechanism to identify problems, they have been very slow to enact changes that actually protect workers. At this plant, there is a system to identify exposed workers by measuring uranium in their urine; that is, after they have been exposed, but the contractor has not tried to determine how people have been exposed and make changes to prevent future dust releases.

In the design and carrying out of epidemiology studies at the Oak Ridge and Fernald plants, the DOE has shown little interest in making use of the results to protect and inform workers in the community. DOE has conducted many studies on the health effects or radiation, but the design of their research has been unfocused and unable to identify problems which remain present.

Each of these workplaces is very diverse, with different exposures from one place to another. Some DOE studies have evaluated large worker populations but have failed to narrow down the population to look at whether the most heavily exposed subgroup is suffering excess disease. By studying large populations where most of the people are not exposed, the good health experience of the majority will mask disease which may be present among the exposed minority. Studies must be designed to identify and evaluate these subgroups, since we know there are sill high exposure jobs, and we must find out as soon as possible the magnitude of the health effects to these highly exposed workers.

For example, workers are still exposed to airborne uranium, and its effects need to be studied in a way which can evaluate whether the standard now used by DOE is adequate. Many old standards like this one have subsequently been found out not to protect workers' health.

Until recently, workers in plant 1 at the Fernald facility have been exposed to levels of airborne uranium far above this old standard. In other areas, workers are exposed to levels slightly below the standard. They need to know if their health is protected by this limit that is now used on Airborne uranium.

One widely discussed DOE study of the Fernald facility by Jerome Wilson in 1983 lumps all chemical operators into the same exposure class, based on occupational title. Their exposures at work, the exposure of these chemicals operators are, in fact, quite varied, depending on in which part of the facility they work. There are approximately six different plants at the Fernald facility.

Because of this lumping of all chemical operators into the same exposure class, the study found only a very limited relationship between uranium exposure and increased disease.

This study did find an overall increased rate of nonmalignant respiratory disease, but DOE, even in this case, failed to take the initiative to inform the workers of these results. They happened to learn indirectly by a conference study by the author.

DOE contractors are also making it difficult for their workers to learn of their own radiation exposures. Just last month at a health and safety class I was teaching in Florida, one of our workers, one of the operators in Oak Ridge explained he is still having trouble

getting information from his employer and DOE on his own recent radiation exposures.

In addition, DOE contractors seem to have an arrogant attitude toward the design of their studies, refusing to allow union health and safety persons to comment on their plans. This is not sound scientific practice, in addition to harming their credibility.

In summary, DOE has been using substantial resources to practice "ivory tower epidemiology", oblivious to public needs and failing to carry out studies which can resolve the most important questions about the relationship of exposure and health. This presents the appearance of a conflict of interest, since the primary work of DOE, of course, is research and production of nuclear materials.

In order to restore public confidence in the scientific basis of radiation protection standards, it is essential that responsibilities of health studies of the effects of radiation be put in an agency whose sole responsibility is public health, such as the Department of Health and Human Services.

Mr. Chairman, that completes my testimony. I would like to append to my testimony a packet of information supporting some of the statements I made.

Senator COCHRAN. By whom?

Mr. WENZL. It is excerpts from several documents on exposures at the Fernald facility.

Senator COCHRAN. We will be happy to have those. We appreciate your providing those to the subcommittee, and they will be included as a part of your testimony.

On page 7 of your statement, Dr. Johnson, you mention as one of the reasons why you think it would be better to have someone other than DOE sponsoring research in this area, you say that:

> If DOE should sponsor research with the results that would do injury to its mission, there would be an obvious motive for suppressing such information.

Do you know of any instance when DOE has suppressed such information?

Dr. JOHNSON. Yes. For example, a study by Dr. Weiss of the Public Health Service of leukemia deaths in Utah. I have the understanding that under AEC auspices that report was not allowed to be circulated.

Senator COCHRAN. Do you know that the Department of Energy suppressed any of that information? I will get to you, Mr. Alvarez. You will get a chance to answer. I will ask each of you.

Dr. JOHNSON. I note that DOE identifies itself with the AEC, and so I would associate the AEC with the DOE.

Senator COCHRAN. Mr. Alvarez, do you know of any such instances?

Mr. ALVAREZ. Yes. I cite two in my testimony, I believe, on page 14. There are others, but I will just simply go into one. In the fall of 1983, I served as a member of an advisory committee convened at the request of the States of South Carolina and Georgia to make recommendations relative to what kinds of epidemiologic studies should be conducted relative to the Savannah River plant in South Carolina.

Prior to that meeting, I discovered, in in-house proceedings, a reference to an internal Du Pont Corp. study that indicated that there

was an increase of leukemia and lung cancer among Du Pont workers at the Savannah River plant when compared to nonnuclear Du Pont workers and members of the public. It was an incidence study.

I notified the chairman of that advisory committee, Dr. Glen Caldwell of the Centers for Disease Control, about the need for our committee to review that study since it was, indeed, some evidence that suggests there might be a problem there.

The meeting took place in October 1983, several weeks before meeting, we received a package to the members of the advisory committee of the Energy Department which contained a study protocol to study the Savannah River plant. They did acknowledge that Du Pont had established an increased risk of leukemia and lung cancer and that the risk was most pronounced among wage employees, however we did not receive the actual study.

At the meeting, we were given a copy of the study by Du Pont that had no author on it which said there was no significant findings. We asked the gentleman whether he authored this paper who was presenting it, Dr. Fairweather. He said no.

We asked, "Well, who did?" He would not reveal other than saying that headquarters wrote this study. We asked him, "When was this study analyzed, when was the study initially done?" He said 1976. "When was this paper presented and reanalyzed?" He said this was a reanalysis of the old study. He said it was reanalyzed a week before. We asked him, "Well, what makes this particular finding different from the original finding?" And he indicated to us that they had changed the test for statistical significance and used the test and the assumption that radiation may not only harm you, but also may be good for you.

Now, this has the effect of slicing data so thin that you can erase a positive, albeit not an overwhelmingly positive finding. The members of that committee issued a report saying that what the Energy Department and Du Pont did was inappropriate and suggested that the Energy Department and Du Pont should be removed from doing this kind of research.

Subsequent to that meeting, I obtained, through a congressional subcommittee, a copy of a report of analysis done by the DOE itself in 1976 upon receipt of the Du Pont study, and that study, that review, done by Dr. Thompkins at Oak Ridge Associated Universities on August 26, 1976 stated, "The apparent risk for leukemia amongst wage employees appears real."

She then urged that, "the arguments against this risk being occupationally related need to be expanded." A second version of her analysis dated August 27 leads to the later statement.

At this time, the August 1976, the original principal investigator of the health and mortality study of Energy Department workers, Dr. Mancuso, had presented positive findings at Hanford, suggesting that the risk of radiation from Hanford appeared to be 10 times greater than the protection currently assumed. Yet the Energy Department felt unnecessary to bring forward these findings at Hanford. That is one recent example.

Senator COCHRAN. Mr. Wenzl, one of the first hearings this subcommittee undertook to conduct under my chairmanship was held at Cincinnati at the request of Senator Glenn to look into the situa-

tion at the Fernald plant. I was just curious as to whether or not you had an opportunity to visit the plant since early 1985, when we had the hearing, and whether or not there has been any improvement in the management of that plant as far as the health hazards are concerned?

Mr. WENZL. I have reviewed the record of that hearing. I think it was perhaps April 1985?

Senator COCHRAN. I think it was in the spring of 1985.

Mr. WENZL. That would mean that two out of my three visits to Fernald have been since then, in August 1985 and this spring, and my experience is that things have not improved significantly. In my comprehensive tour in August 1985, there were still significant problems with airborne uranium, and likewise, significant problems with the contractors in DOE not being able to say what the magnitude of the problems was or what they planned to do about them.

Senator GLENN. When was your last visit there? You said August 1985. The hearing was in April, when the process of changing the contractor for the plant was underway. Have you been there more recently?

Mr. WENZL. My last visit has been since Westinghouse took over. I believe Westinghouse took over in December of the plant. I think my last visit was in March or April of this year.

Senator GLENN. March of this year

Senator COCHRAN. Senator Glenn.

Senator GLENN. I only have a couple of questions here. One, I was concerned about this thing of some of the records being destroyed. What was the reason given for that? Did they run out of their statute of limitations, where you can destroy records, or was there a move to get these records out of the file ahead of time and do away with them? Do you have any indication of what happened there?

Mr. ALVAREZ. I can only sort of provide a chronology of events about this matter. In September 1977, Dr. Thomas Mancuso, who was the principal investigator that held the contract for the health and mortality studies from 1964 until 1977, presented a final report to the Energy Department called "Final Report No. 13." In that report, he listed the data that he had assembled over the period that he held this contract, and included in his report was reference to 41 filing cabinets of medical records of Oak Ridge residents which he specifically described as "source data".

Subsequent to that time, Dr. Mancuso had heard from a former employee of his who was working at Oak Ridge that the investigators at the Oak Ridge Associated Universities who had taken over his contract were destroying his data, but this person who had contacted him had since left and could not be traced.

Senator GLENN. I was getting at this: We are required to keep certain records in certain departments for a certain period of time. Then they are destroyed unless somebody is specifically requested to keep them. I am just trying to pin down whether this was a deliberate act of doing away with data or whether it was a 5-year period.

Mr. ALVAREZ. It is unclear whether it was carelessness. What did happen is 21 our of 41 filing cabinets were destroyed and that a

new epidemiologist joined the Oak Ridge Associated Universities staff and put a stop to it, indicating that there was some benefit to this.

But the fact remains is that these filing cabinets were listed in the report and described as such as source data for purposes of research by the original principal investigators. So they had at least formal research knowledge that these data had been set aside.

The newspaper accounts concerning this matter which were reported last fall presented the position of part of Oak Ridge Associated Universities that they were simply requested by Oak Ridge Hospital to destroy them because they did not have any space. ORAU, at least if they read that report, were aware these data were set aside for research.

Dr. JOHNSON. In view of the very long incubation period for radiation-induced cancers—they may be produced after 30 to 40 years—the records should be kept throughout the lifetime of the employee.

Senator GLENN. Is that something that needs to be corrected, or is that something we need to correct?

Dr. JOHNSON. We need to correct that.

Senator GLENN. What is the normal length of time that is required now to keep personal records, by regulation?

Dr. JOHNSON. I think that in some places it is 7 years; in other places it is less; but for radiation exposures, I think it should be for the lifetime of the person.

Senator GLENN. I agree with you completely. I am not questioning your judgment there. I think you are absolutely right, because these studies ought to go on for the lifetime of the individuals and we ought to keep the records, I would think, just to get the data we need long-term.

Mr. ALVAREZ. If I may add to that, the whole mechanism upon which the data is assembled deserves further examination. The contractors who run these plants have pretty much the sole responsibility for assembling the data under the supervision of Oak Ridge Associated Universities.

Despite its title, Oak Ridge Associated Universities is a Government-owned contracted facility that predominantly employs DOE research and management personnel. This data is then processed through ORAU and sent out to researchers without personal identifiers.

That is sort of a block box approach. The researchers whose job it is to analyze these data have no way to determine whether these data are accurate or complete.

When NIOSH does its health evaluations or health studies, their investigators are given access to the source data, and there is a potential conflict of interest here, because these data have more than one use; they also can serve as evidence in legal proceedings regarding compensation claims, and to have people who may be or entities, rather, who may be sued because of a claim, responsibility for assembling and collection of these data is, in a way, like asking the asbestos industry to be the sole determinant of data for asbestos studies.

Senator GLENN. Or the tobacco industry to be the sole investigator of cancer research.

Mr. Wenzl, your position you have taken on this, has it been approved, or do you have agreement from other unions? Has AFL–CIO in general endorsed your statement here as to the view of your union on this?

Mr. WENZL. No, I don't believe the AFL–CIO in general has, but these 15 unions, these so-called Atomic Trade and Labor Councils in Oak Ridge and Fernald, made up, as I said, of 14 different unions, as I said, both of those councils have approved our position.

Senator GLENN. Dr. Johnson, you had a point.

Dr. JOHNSON. Just a quick comment to agree with Bob. Most studies of workers allow the researcher direct access to employment and exposure records. This is apparently not the case in the studies at DOE plants, where the researchers are given predigested data, screened by management, I presume.

Senator GLENN. Just one other question. Is this a standard form or standard data base that is used, a standard reporting procedure that has become common in radiation studies that should be adopted as the norm, as the standard. Is DOD going along with that, if there is such a form, or is somebody following DOD's lead, or is HHS, the Center for Disease Control with their expertise, do they have a certain form and everybody else uses a different one?

I am thinking of this data base, because we need the data base, and those records should not be destroyed, and CDC, I think, is usually responsible for that kind of a general population data base. There should be some uniform reporting system if we are to put this into the computer and have it as a data base in the future.

Dr. JOHNSON. I know that there is variation in recordkeeping systems between plants. There are a number of types of such records, and in general, those records are incomplete. There may be gaps of years, where there is no data present for plutonium exposures of plutonium workers. In no cases have I seen records, for example, of personal air monitors; which show much higher levels of nuclides in the air than do room air monitors; or of the use of nasal swabs; and there is virtually no record of fecal samples for uranium workers, which indicate the amount that person has inhaled. In general, the records are not complete.

Senator GLENN. I have no further questions. Thank you, Senator.

Senator COCHRAN. Thank you very much for appearing before the subcommittee this morning. We appreciate your presence and your contribution to our hearing.

Our next panel consists of witnesses from the Department of Energy, Dr. Mary L. Walker, who is Assistant Secretary for Environment, Safety and Health; Dr. Trivelpiece, who is the Director of the Office of Energy Research; and Dr. Robert Goldsmith, who is the epidemiology program manager.

We welcome you all to the subcommittee and express our thanks for your being here and helping us with the hearing.

We have copies of the statements from each witness, and we will make those a part of the record in full. We hope you will make whatever summary comments from your statement that you care to. That will give us an opportunity to discuss your testimony.

Let's start with Ms. Walker. You may proceed.

TESTIMONY OF MARY L. WALKER, ASSISTANT SECRETARY FOR ENVIRONMENT, SAFETY, AND HEALTH, DEPARTMENT OF ENERGY,[1] ACCOMPANIED BY ALVIN W. TRIVELPIECE, PH.D., DIRECTOR, OFFICE OF ENERGY RESEARCH,[2] AND ROBERT GOLDSMITH, PH.D., EPIDEMIOLOGY PROGRAM MANAGER [3]

Ms. WALKER. Thank you, Mr. Chairman, and members of the committee. You do have my written statement. I will attempt to summarize it. I am pleased to be here today to discuss the role of the Office of Environment, Safety, and Health [ESH] at the Department of Energy and to assure you of Secretary Herrington's personal commitment to a quality environment and to the safety and health of our workers and the public.

For several reasons, I believe it is both unnecessary and unwise to transfer the epidemiological function from the Department of Energy to another agency. But first let me emphasize the different roles of my office and the Office of Energy Research concerning health and safety.

The role of my office is to assure the adequate protection of the environment and the health and safety of our workers and the public. The Office of Energy Research is responsible for research to determine if health problems exist in the vicinity of DOE sites, and, if so, to identify the cause.

Specifically, it is my job to assure that DOE's activities comply with all applicable environmental laws and regulations and that health and safety risks are reduced to acceptable levels. The Department has an excellent health and safety record which is demonstrated by comparisons with the record of the private sector.

I intend to do everything possible to assure that this record is maintained and that all improvements are made where they can be made. Environment, Safety, and Health is also responsible for developing policies, standards and procedures for the health and safety of our workers and the public near our facilities. Our standards incorporate applicable EPA requirements, are comparable to NRC standards, and are consistent with recommendations of the National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection.

Results from DOE's epidemiological studies contribute to the overall data base used by the scientific community and support the standard setting and risk assessment process. DOE maintains a monitoring and exposure reporting program at each of DOE's sites to determine compliance with safety and health protection requirements.

Such data are used in epidemiological studies in various ways. For example, monitoring and exposure information can be used to determine the need for and the feasibility of conducting these epidemiological studies. ESH benefits from information provided by DOE's epidemiological studies. In turn, the Office of Energy Research benefits from the monitoring and exposure data-gathering program that we have at the Department.

I believe it is important to keep this function within the Department to help define needs, prioritize studies and eliminate duplication of effort.

Thank you.

[1] Ms. Walker's prepared statement appears on p. 135.
[2] Mr. Trivelpiece's prepared statement, with attachments appears on p. 144.
[3] Mr. Goldsmith's prepared statement, with attachments, appears on p. 191.

Senator COCHRAN. Thank you very much, Ms. Walker.

Let's now hear from Dr. Alvin Trivelpiece.

Mr. TRIVELPIECE. Thank you, Mr. Chairman, Senator Glenn. It is a pleasure to be here today to testify on S. 525 because of the importance that I attach to free and unfettered scientific inquiry into the cause-and-effect relationships between radiation and chemicals and cancer and other diseases, radiation and chemistry and what to do about them.

We are concerned about the consequence of these on DOE workers and the population at large. In that regard, I would like to point out that the 1947 AEC Act contained implicitly and explicitly two strategies: One of these is offensive, and the other is defensive. The offensive strategy, in effect, say that nuclear materials are a new tool that we can use to the benefit of mankind in the division of biology and medicine.

The AEC at that time set about to discover what these were and to make them available to the public at large. As a result of that effort, and things that are still going on today in programs that I manage, more than 100 million people a year in the United States receive either therapy or diagnosis involving some aspect of nuclear medicine or its applications. All of these activities owe their origins to activities that have created events and things that were supported by the AEC and its successor agencies.

In the defensive category, it was clear that there were some risks involved in nuclear materials, and the charge was to put together the capability of determining what those risks were and establishing procedures and processes by which those materials could be handled safely.

The United States and world standards are based on this early and continued work. As a consequence, we know more about nuclear substances and their risks than we do about any other substance. That is a remarkable fact. It is against this backdrop of greater than 40 years of work by DOE and the AEC that we are strongly opposed to the transfer of these activities from the Department of the Health and Human Services Department.

With respect to these things that I have talked about, the offensive and defensive strategy, I would like to have introduced into the record the exact language from the AEC Act, and there are some things that expand on this in this small booklet.[1] With your permission, Mr. Chairman, I would like to have it incorporated as part of the record of my testimony.

Senator COCHRAN. Without objection, that will be made a part of the record.

Mr. TRIVELPIECE. You might wonder why the Department of Energy takes such a strong stand in opposing this legislation when, in effect, what is involved is one employee who is a Federal employee and at most, $17 million of budget, which is even debatable in that amount. It is because the Secretary of Energy has an obligation to ensure the health and safety of the workplace, the workers that work for DOE and its subordinate organizations, and in

[1] The booklet referred to appears on p. 255.

order to carry it out, he needs the ability to have certain information.

The objective of the legislation that is very well-intentioned in that regard, and in that sense, we would support it. But the consequences, I think, of this legislation may be substantially different from those which are intended. It is these unintended consequences that I would like to address for a few minutes because I certainly have trouble believing that it is the intent to deny the Secretary of Energy a means by which to carry out the studies necessary to determine if there is any unwarranted risk in the workplace and then to take corresponding action related to that.

Furthermore, the activities that we are discussing here are funded and managed as an independent part of the collection of basic research studies in the Office of Energy Research, for which I am responsible.

They are not constrained in any way that I am aware of. If there is any evidence to the contrary that anyone can supply, I would appreciate it if they would do so directly to the Inspector General of the Department of Energy so appropriate action might be taken. Likewise, if the scientific work is fettered in any way or if it is not excellent in the manner that I regard as appropriate, then I would appreciate hearing about it, so I might take appropriate and corrective action.

I would like to remind the subcommittee of something that Mary Walker has just said, and that is the Office of Energy Research does not make or enforce any of the health and safety standards. I think the allegations, which I believe to be unsupported, that this work that we support has been altered or modified in any way to make those standards less difficult is somewhat insulting to the integrity of the scientists who have done this work over many years.

Another intended consequence, I think, is on future epidemiology studies that might be done by the Department. For example, we might do a study on chemistry, which S. 525 does not prohibit. In doing an epidemiologic study on chemistry, there might be the compounding factor of radiation, not to take radiation into account in such a study would make it scientifically irrelevant.

So it is likewise true that you can't do a study of radiation without taking into account chemistry and smoking and other compounding factors. It goes as a whole. The question, in my mind, is whether there is a way to satisfy some of the goals of S. 525 without incurring any of the unintended consequences? If the studies are as important as I believe they are, and I hope that you believe they are, then the objectives are really to try to create a climate of free and unfettered inquiry in which the causes and effects of radiation, chemistry, and so on can be studied, the results published in open scientific literature, and such results can be taken into account and appropriate action taken as a result thereof. To further this objective, I would like to suggest that the Health and Human Services Department be asked to conduct whatever collateral studies might be appropriate and initiate them in any area that the Department is currently doing. This might result in a minor amount of duplication.

But if these objectives are as important as alleged, and I believe that they are, then we would welcome such studies.

In addition, there is a concern that perhaps these studies aren't as objective as they should be within the Department. So I would be willing, in terms of the Federal Advisory Committee Act, to try to put together an appropriate outside body to review what we are doing and to determine whether or not what we are doing is independent, free, and unfettered scientific inquiry on cause-and-effect relationships between radiation, cancer and other diseases.

In summary, I would like to emphasize essentially three points: Let DOE continue what it is doing in its epidemiology work; ask the Health and Human Services Department to engage in independent work that may be collateral in whatever areas they deem appropriate to back up any of the DOE studies; and third, let us explore the possibility of an appropriate advisory function that would help alleviate the concerns, I think, that prompted the drafting of S. 525.

Thank you, Mr. Chairman.

Senator COCHRAN. Thank you, Dr, Trivelpiece.

Dr. Robert Goldsmith is the other member of our panel. You may proceed with your statement.

Mr. GOLDSMITH. Thank you, Mr. Chairman. I will keep my remarks very brief. I would just like to say as the person closets to the DOE epidemiology program and as the person responsible for its management, that in my opinion, transferring these studies to another agency would be detrimental to them, and ultimately to the subjects of the studies and to those who would use the results of the studies.

The Department of Energy and its predecessor agencies have demonstrated a long-term commitment to radioepidemiologic studies of their employees and of other important human populations.

I do not believe that any other agency would continue this type of commitment. The transfer would entail an enormous amount of time and effort, much of it duplicative. There are several impediments to accomplishing the transfer, such as contractual agreements with States to provide death certificates, which will cause substantial delay in restarting studies, should they be transferred.

In addition, we have in place now a communication network to assure that workers and the public are involved in and informed about our studies. The transfer would remove the studies from this network. This is particularly unfortunate, because I believe that we really have begun to improve our credibility with the public and our workers.

Thank you. This concludes my statement. I would be pleased to answer any questions you may have.

Senator COCHRAN. Thanks, Dr. Goldsmith.

Ms. Walker, I wonder whether or not you know of any effort at the Department of Energy at the Secretary's level or in any other management area of the Department to review studies and make sure that the results are consistent with Administration policy in any way?

Ms. WALKER. No. I am not aware of anything like that in terms of policy, no. Obviously, any time there is a study, I want my staff to review it to make sure that whatever findings it has made are known to us because we are, again, responsible for assuring the health and safety of the workers and the public.

Senator COCHRAN. Is there any effort to monitor studies that are ongoing with a view toward suppressing any information that might be considered inconsistent with nuclear promotion interests?

Ms. WALKER. No, not any that I have ever been made aware of.

Senator COCHRAN. I wonder, in the conduct of these research efforts, if there are others, outside of government, who undertake to do such studies. Is there anything to prevent foundations or universities or any private groups from conducting epidemiological studies in these or any other areas that might interest the general public or the scientific community as a whole?

Mr. TRIVELPIECE. Not that I am aware of, Mr. Chairman. I think if such a group were to propose, through an unsolicited proposal, a study that we would regard as being scientifically appropriate and met peer review standards, that we would probably try to seek to find the funds to help get it done. It would obviously have to be to objective scientific standards.

Senator COCHRAN. Is the Government the only source of funds for supporting research in this general area here in the United States?

Mr. TRIVELPIECE. I am not sure. Perhaps Dr. Goldsmith knows more about this.

Mr. GOLDSMITH. No, there has been other precedents. The rubber industry funds, through union dues, studies of rubber workers. Certainly, the same thing could be done.

Senator COCHRAN. At the present time are there any major studies being undertaken that do not have the support of the Federal Government?

Mr. TRIVELPIECE. Before DOE, or in general?

Senator COCHRAN. In the radiation area, the nuclear area, the effects of nuclear radiation on public health. Are there any major studies being undertaken in this area by anyone which is not being supported by the Federal Government?

Mr. TRIVELPIECE. Not that I am aware of, but we could certainly check and provide a confirming answer for the record on that.

Senator COCHRAN. So if any major studies along these lines are conducted, then we can conclude that they would probably be funded by the Federal Government and that those funding programs would be administered by the Department of Energy; is that right?

Mr. TRIVELPIECE. Or there could be funding through some other Federal agency.

Senator COCHRAN. Are any other Federal agencies providing funds in this area at the present time that you know of?

Mr. GOLDSMITH. Yes; the National Institutes of Health has a radiation epidemiology program, but for the most part, they are interested in populations who have been exposed either therapeutically or diagnostically to medical radiation.

Senator COCHRAN. The forming of an advisory committee or a review committee, a peer committee, to monitor the results of these studies is something that sounds to me as though it might be a good idea. Has this been discussed in the scientific community or among those who are involved, Dr. Trivelpiece?

Mr. TRIVELPIECE. No; although earlier, a few years ago, I did ask the then recently established Health and Environmental Research

Advisory Committee to look into the epidemiology programs which the Department supports with much the same questions that are being addressed here today. Some of the conclusions of that report are part of my written statement for this hearing. It would be possible, either as a part of that advisory committee or any other departmental advisory committee, in terms of the Federal Advisory Committee Act, to carry out such a function.

We haven't discussed this with the scientific community at large, because the establishment of such an advisory committee is a policy decision of the Department. But we would be willing to explore it.

Senator COCHRAN. I was looking at a list of studies that were undertaken under the authority of the Department of Energy. These are radiation epidemiological studies by such entities as Johns Hopkins University; the National Academy of Sciences; the University of New Mexico and the Los Alamos National Lab. Are these considered, in your judgment, to be reputable institutions with good reputations for quality work, or not?

Mr. TRIVELPIECE. I would be hard pressed to express an opinion to the contrary. They are outstanding institutions.

Senator COCHRAN. Let me ask you this: Is there any safeguard or procedure developed to protect the independence of the work done by scientists at those institutions in these radiation studies?

Mr. TRIVELPIECE. Well, it is more the contrary. I don't think there is any mechanism in place by which to fetter them in any way. The proposals are made; the work is carried out; the results are made available through published results in peer review journals.

As I said earlier, if anything is being withheld, I would like to know about it, because that certainly is not the intention nor the instruction.

Senator COCHRAN. I wonder if, at the Department level, at the Secretary's level or to your knowledge, Mr. Walker, has anyone brought to your attention any effort by anyone in the Department of Energy or in the Federal Government to interfere in any way with the independent research being done at any of these institutions?

Ms. WALKER. No.

Senator COCHRAN. Senator Glenn.

Senator GLENN. Thank you, Mr. Chairman.

In response, very briefly, Dr. Trivelpiece, to your comment about intent to deny DOE facilities a right to review their own process, I don't remember the exact statement you made along that line, and to the concern that DOE's integrity was being questioned, there is no intent to deny the Department of Energy in any way, shape or form the right to run their own monitoring and run their own safety procedures and so on.

Nor am I questioning the integrity of people involved in any way, shape or form there. So I want to clear that up. But DOE's mission is production, is it not? Safety is not their primary mission; it is production of this material. Commercial plants that were mentioned a little while ago here don't exactly do their own monitoring. They do their own monitoring in-house, but then they have

other people come in and check from NRC, and that is basically what we are talking about here.

We would think it was ridiculous if we said we will let the tobacco industry do the research on monitoring the health patterns of heavy smokers and report to the public on the dangers. We don't let the trucking industry set all the standards for their own operation. We have other people do that. We don't have Wall Street, in a completely different area, set all their own rules with regard to stocks in the stock market and so on. We have other people doing this checking from outside, even though there are people on the inside who do internal checking within their own career specialties there.

And research is not the only issue. There is also DOE's performance on safety. I have been following this for roughly 10 years, so a lot of this has not happened on your watch, any of you here. What has happened is that back in 1976, as reported in the GAO report here, in 1976, it was a requirement that DOE place all their nuclear defense facilities under an SAR process, safety analysis review process.

That had previously been required for DOE reactors, but all defense facilities then were to come under this same process in 1976. Ten years later we are still waiting for this process to be completed satisfactorily.

Meanwhile, we turn up problems like Fernald in my home State of Ohio. We had hearings out there, as the chairman mentioned. The GAO checked up on DOE's performance in 1981, and in 1981, they found DOE had not been completing the reviews in a timely fashion, as the GAO report said.

In a 1983 GAO report, there was some progress reported but it said that staffing limitations could delay the progress for some existing facilities. GAO states in the present 1986 report, "In general, DOE officials told us that higher priority work and limited resources have delayed the approval process. DOE officials also told us that all three safety analysis reviews for the aforementioned should be approved by mid-1987."

What that tells me is if we are talking about not completing the safety analysis reviews and delaying completing those since 1976, that the DOE was supposed to be working on these things, it means that safety has not been priority No. 1 at DOE. That is just the nub of it.

I don't want to see a Chernobyl in the United States of America, and you don't, either; nobody in this room does, obviously. So we are united on that. How do we get to safety? Having safety analysis reviews, it seems to me, is important.

They have been delayed because of budgetary restrictions or people or whatever.

Now, back to the research question. There have been allegations by Dr. Mancuso. That goes back before your watch, I agree, but he apparently planned to publish research results that were adverse to DOE's wishes at the time, and he was pulled out, kicked out, the job given to somebody else when that became known, where allegations of important data needed for performing meaningful epidemiological studies of health effects from radiation exposure has been

lost or destroyed. I can't imagine that in a time when we are trying to get a better data base.

And there have been allegations that subtle pressures are placed on researchers supported by DOE to produce results in keeping with perhaps a preconceived idea of the health effects of radiation; and allegations that DOE has a history going back to AEC days, way before any of you were involved with it, of constantly down-playing adverse facts involving radiation.

What this has boiled down to is a public mistrust of DOE-sponsored research results, no matter how careful the peer review. So what is at issue is the credibility of DOE in the eyes of the public given the history of the coverups in Utah during the days of nuclear testing, the Mancuso affairs, the destruction of data, the elaborate down-playing of risks.

So I just think an outside review would help on this. I am not trying to cut out your internal review at all. It just seems to me common sense that maybe you would even want to request another outfit to monitor what you were doing. That is what we are proposing, basically, in this bill; we are saying that the people that are responsible for the production and that production goals to be met should not be under those pressures and at the same time be in charge of reviewing the safety or health aspects of what the production is doing. That is basically what this bill is all about.

So does anybody want to respond to that? That is not exactly a question.

Mr. TRIVELPIECE. You directed your remarks to me.

Senator GLENN. Any one of you.

Mr. TRIVELPIECE. They involve more the safety issues than they do the epidemiological research efforts. First, to some extent, I disagree respectfully with what your bill would actually accomplish as distinct from what you just said that you believe it would accomplish. You mentioned the tobacco industry. I agree; perhaps one would not necessarily take at face value research sponsored by the tobacco industry concerning the risks of smoking.

On the other hand, would you deny the tobacco industry the right to expend their own funds carrying out fundamental research which can then be examined in the scientific marketplace to determine whether or not it is valid or rubbish?

To some extent, that is what your bill is saying, you are denying the Department of Energy the right to expend the funds necessary to determine the basic cause-and-effect relationships between radiation, disease, and cancer. I think that is an inappropriate thing to do.

More of your concern seems to be on the management of the safety aspects of the Department, and that is not part of the basic research activities that I am responsible for.

Senator GLENN. If I could add to that, your organization within the U.S. Government is involved with monitoring similar public health and safety matters as are done by the Health and Human Services Department, and the Center for Disease Control in Atlanta, which has their people analyze radiation hazards and so on. They are the ones trying to analyze the data, get the whole thing together and monitor what is safe for the whole country. That is

why I think it is appropriate they be given the primary responsibility.

I say primary, because you certainly should be permitted, within DOE—and I repeat this again, even though I said it before—to do your own monitoring, your in-house monitoring, but I think it proves, in light of what has happened in the last 10 years, I think it is prudent that we have someone else doing the analysis on this also.

Mr. TRIVELPIECE. But your bill, as I understand it, would deny us the opportunity to carry out basic research that would seek to understand cause-and-effect relationships between cancer and radiation.

Senator GLENN. Your primary basic research organizations in this area should be within CDC and the HHS.

Mr. TRIVELPIECE. The Department of Energy initiated this field; it has been the primary supporter of it. What we know about radiation, its cause-and-effect relationships with cancer, is due to, as I mentioned earlier, the AEC Act.

Health and Human Services and the other organizations entered into this later. They have done a fine job. There is absolutely no reason to criticize any of their research. I don't even have any trouble with their being primary, but I do have trouble with the thought that you would deny the Secretary the tools with which to explore these things in those areas for which he has primary responsibility. The Secretary should be encouraged to conduct independent monitoring of safety and the conduct of health and safety activities such as safety reviews.

Senator GLENN. As I mentioned, I think we have a real credibility problem within DOE going way back. We have been unable to get the safety reviews through DOE for 10 years.

Mr. TRIVELPIECE. But that is a different problem than the conduct of the basic research into molecular and cellular bases for relating radiation or chemicals to cancer risks and/or disease.

Senator GLENN. Madam Secretary, why can't we get these safety analysis reviews through? I don't know how long you have had the job.

Ms. WALKER. Three months.

Senator GLENN. Who had the responsibility for it for the last 5 years that didn't do it?

Ms. WALKER. Let me just say this, Mr. Senator. I cannot respond to the specific safety analysis reports that you mentioned, as to whether or not they are in a state of revision or what the reason is that, if they have not been finalized. What I can tell you is this: That for all our facilities, we have approved technical specifications which set forth the elements that are deemed necessary so that the facility is not only designed, but is operated in a safe manner.

That is the foundation upon which we rest our belief that our operations are safe. In addition, we have a thorough review, a continual review of both the design and the operation of all of our facilities starting at the field office level and through my independent oversight operation at headquarters. On a continuing basis, my office does about 100 appraisals a year of our facilities, in addition to which the Secretary has initiated new technical safety appraisals which are comprehensive, multidisciplined looks at each of our

high- and moderate-hazard nuclear facilities for an indepth safety review. Out of those appraisals, both the new initiatives that Secretary Herrington has brought into play, plus the additional ones that are ongoing, recommendations are made on an ongoing, forthcoming basis that are implemented.

So there is a continual updating and scouring, if you will, of our operations so that they continue not only to be safe, but are brought safer.

Through other programs, such as the ALARA, as low as reasonably achievable programs, we continue to seek ways to reduce exposures, even below those that would be in compliance with standards.

I am not saying because you feel there are safety analysis reports that have not been completed that this is not true, nor am I trying to minimize it; however it is not because safety isn't paramount at the Department or that we don't have criteria and reviews in place. So we are assuring you and the public that we operate in a safe manner. Last, I would look to our safety statistics, which always have been continually better than the private sector.

For the record itself, I won't tell you there haven't been instances or in the past, certainly at the beginning of the nuclear business, which we would all like not to have happened, but our record has been an excellent one. I think the mechanisms we have in place have demonstrated that our safety statistics are good and that what we are doing is meaningful and appropriate.

Senator GLENN. Do you think all these instances that we had mentioned here, had we had safety analysis reviews and had them in place and had the facilities monitored and everything, that those would have happened?

Ms. WALKER. I am not certain what instances you are referring to, Senator.

Senator GLENN. The draft GAO report says, and I quote, "It is difficult for DOE to conclude, on the basis of its safety analysis review, that the risk of operating its nuclear facilities is acceptable."

Ms. WALKER. First of all, Senator, I have to apologize. I only received the GAO report late last night; my staff, as well. We have not had a chance to review it. That review, obviously, has begun, and we will be able to provide more details at a later date.[1] I cannot tell you to what degree certain safety analysis reports, if they have not been made final, would cause us to reach that conclusion.

What I am saying is we can conclude our facilities are being operated in a safe manner. I do not believe the safety analysis reports are needed to justify that.

What I am referring to is both the technical specifications, the appraisals, management oversight and a whole defense, indepth concept that we have at Department of Energy that assures us, and we believe you and the public, that our facilities are being operated in a safe manner.

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[1] The Department of Energy review may be found on p. 272.

I don't know that it is critical to that objective for certain safety analysis reports to be made final as of this date. Again, I don't know whether they are in the process of being revised or what accounts for that. I am just saying that is not what we are relying on in assuring you that we are operating our facilities in a safe manner.

Senator GLENN. There are four basic things that the GAO report found. They found, in their words, that, "Safety analysis reviews have not been approved by DOE for three of the eight facilities, each of which has the potential for significant onsite or offsite releases of radioactive material in a major accident."

No. 2, on the extent to which facilities were compared against safety design criteria that you mentioned, it says, "The extent to which the facilities were compared against safety design criteria in the reviews varied considerably between the facilities we examined, with some providing a detailed comparison, and others providing little or no comparison."

No. 3, "Different approaches were used in the reviews to identify and analyze potential accidents at DOE facilities, with some approaches being more comprehensive than others."

And No. 4, "All the safety analysis reviews exams were or are being reviewed internally and approved internally within DOE, which does not represent an independent review process."

In the next paragraph down below this, they say, in part—this is not all of it—they start out in the next paragraph. This is in 1976, but of the reviews we made in 1981 and 1983 and still have problems, they say, "In general, DOE officials told us that higher priority work and limited resources delayed the approval process."

What can be higher priority than having the final analysis of safety analysis reviews, which is supposed to be the thing that tied all these things together you are talking about, your safety programs, your backup programs, all the things you just mentioned? If they are satisfactory, that was supposed to come together in a safety analysis review. They were supposed to put that out, have it out for comment, critique and criticism to see if anybody criticizes this so we don't have a Chernobyl in this country.

That hasn't been done, that has been held up, and we are saying we don't have the resources; we have higher priorities and limited resources. I can't imagine anything that should deserve higher attention, is a higher priority than that, than trying to get the safety and the resources to do it. What is going on?

Ms. WALKER. I can agree with you, Senator. There should be no higher priority than safety. I believe that is the highest priority at the agency, and what other priorities might have kept somebody from finalizing a particular component of our safety program or a particular document, I don't know. We will have to review the report and respond.

The safety analysis reports are one component of the safety program. I realize it is an important component, and I realize that you would like to see this effort completed. Again, I don't know why some have not been, as I haven't reviewed this yet, but as to the other things you mentioned, I might be able to add some light here.

Different facilities, obviously, present different risks. Some are considered by our agency to be high hazard, some moderate hazard

based on potential accident scenarios, potential risks. So to some degree, we may provide a different analysis on some than others.

I know some of our risk assessments have been in much greater depth for some of our higher hazard facilities. You talked about independent review.

My office, the Office of Environment, Safety and Health, which is independent of any other office in the Department, is independent in the sense that I am not tied to any program, I don't have any programmatic budget constraints or anything like that. It reports directly to the Secretary, performs an independent review of facilities, and under the new revised safety orders that have been revised in the last year, we have independent concurrent authority over safety analysis reports. Thus we independently review them and concur in them as to whether we believe they have demonstrted the requisite level of analysis.

So I believe that there has been the kind of review that you have been looking for, and of course, we will be happy to provide additional information on this for the record.

Senator GLENN. Let me go to a different area. We have the Nuclear Safety Program Appraisal that the Albuquerque operations office put out in June of 1985, just about a year ago, by the DOE Office of Environment, Safety and Health, the predecessor of your division. The document is marked, "Not for public dissemination."

We were able to get this thing cleared. There is nothing classified in it of a national security nature, nor does it contain restricted data of any kind, nuclear data. What it does contain, among other things, is a very critical appraisal of the way the Albuquerque operations office has carried out its responsibilities to assure that the nine DOE contractors were providing adequate radiation protection for workers.

I won't list all of them. One of them is the Mound facility back in Ohio, also. I do not question your commitment or Secretary Herrington's or anyone's at the table here this morning. But it just seems to me that DOE's credibility in the area of health and safety for the workers in public health has been badly damaged.

Frankly, DOE, as I see it, has no business being the prime supporter of research in this field as long as the main mission is nuclear production. I know you all have a personal commitment to safety, but I just don't think that personal commitment to safety is enough, and also your personal commitment is not enough when one administration or another puts out different regulations and executive orders rather than having this thing locked into law so we can be sure for the future.

Ms. WALKER. Senator Glenn, if I might comment on our safety reviews, while I couldn't speak to the specifics, we are attempting to make all of our technical safety appraisals Under Secretary Herrington's new initiative available for public review, so as to minimize their potential for being classified. I do know sometimes reports have been made classified or have been required to be classified based on the entirety of the report. I don't know if that was the case there.

But obviously, it is our intention to share as much information as we can on our reviews. I think it is unfair to criticize the Department and my office, in particular, for being candid, forthright,

and very hard on operations when we find an area they should be improving in, and at the time tell us, when you do find that candor and that criticism, which only leads to a better safety performance because they are in the process of fixing the problems we point out now, and now say we shouldn't be conducting the reviews because of what we find.

The whole purpose of my office is that I have the freedom to be critical. It is important that I be able to do that. When I am critical in a report, it is because I want them to fix something. I hope you share the desire that we can continue that.

Senator GLENN. I want you to do anything you can possibly do, and bless you, if it is going to provide more safety for our nuclear facilities, whether they are prodution facilities or whatever kind of facilities. We just find it very difficult; we just can't see why these safety analysis reviews, for instance, have been delayed 10 years.

Ms. WALKER. I will look into that.[1]

Senator GLENN. Ten years, and you are saying the overall bits and pieces are being looked at. But the overall design was supposed to be tied into safety analysis and review.

Dr. Trivelpiece, I don't know when your watch started over there, but you were around when this Albuquerque report was made. Why was it classified? Why was it restricted from the public, do you know?

Mr. TRIVELPIECE. No idea.

Senator GLENN. Do you know, Dr. Goldsmith?

Mr. GOLDSMITH. No.

Ms. WALKER. I can provide that for the record.

[Subsequent to the hearing the following was submitted:]

Concerning the question on the reasons for classifying the AL appraisal report, an earlier draft was thougth to contain sensitive information. However, the current draft has been reviewed by the DOE Office of Classification and we have been advised that the UCNI notice is no longer necessary.

Senator GLENN. We would welcome that. There was nothing in the report of a national security nature, but because it looked like it was critical, it looked like it was being swept under the rug.

Ms. WALKER. I can give you volumes where we have been critical and they have not been withheld from public review. That is certainly not the criteria for why it was classified.

Senator GLENN. Put a priority on these things, and let people see there is a real review.

Ms. WALKER. I just received the report from GAO last night.

Senator GLENN. I understand you can't digest everything in it overnight. I know that. I appreciate that.

Senator COCHRAN. I think it should be pointed out that the hearing today was called to review the proposed legislation to transfer authority from the Department of Energy to the Department of Health and Human Services for conducting radiation research and that this information and the GAO report the Senator is referring to was not discussed with either the chairman or with any of the witnesses as something that would be reviewed at the hearing.

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[1] See p. 271.

I have no objection to a discussion of this at this hearing, of course. We do want to make sure that every effort is made to have the highest degree of safety possible at every Department of Energy nuclear facility, whether it is contractor-operated or it is under the direct management of the Department of Energy. I share that concern and hope.

But because this was not made available to the Department, I hope that we can have a review undertaken of the report by the Department and a response filed so that it can be included in the record of the hearing.[1]

As a matter of fact, GAO, according to its language here in the report, was asked by the Senator not to provide the agency with a copy for comment. That should be pointed out. I will read from the report. "As requested, we did not obtain official agency comments on a draft of this report."

We presume that "as requested" means it was requested by those who requested the report, and that was the ranking minority member of this subcommittee. So now that the information is available, we hope you will be able to comment for the record.

In connection with the——

Senator GLENN. Would the Senator yield?

Senator COCHRAN. Not at this moment.

In connection with the safety analysis reviews at contractor-operated facilities, it is my understanding that new procedures have been put in place, particularly since this subcommittee's hearing in Ohio, to try to acquaint workers with radiation information; with safety procedures to try to do a better job at these contractor-operated facilities; with communication, providing information to workers.

Mr. Goldsmith, is that correct? Are we being provided accurate information by the Department that there are new procedures in place to try to help alleviate some of these safety probelms that have been identified previously?

Mr. GOLDSMITH. Again, that is in the purview of the Environment, Safety, and Health Office. As far as epidemiologic research studies are concerned, we have developed what we call an epidemiology outreach program which allows workers to visit in places where the research is being conducted; it gives them access to draft reports; it provides a telephone number where they can contact the principal investigators conducting the studies; gives them the chance to suggest new studies which might be initiated and so on. This is in effect right now.

Senator COCHRAN. Senator Glenn?

Senator GLENN. Thank you. I just wanted to comment on the comment that the chairman made about requesting that this not be given to the agency. Let me read that whole paragraph, if I may, because it puts a little different light on that. I think the chairman read the first sentence and not the rest of it. I quote, "As requested, we did not obtain official agency comments on a draft of this report. However, we discussed the contents of this report with

[1] See p. 271.

agency officials as it was being developed and incorporated their views as appropriate."

Then, "Unless you publicly announce its comments earlier, we do not plan to distribute this report until 30 days from its issuance date. At that time, we will send copies to the Secretary and other interested parties."

Last night was the date of issue for you. That is quite standard, that paragraph, from GAO reports. There was no intent to blindside the agency, and I don't want to do that; I am not trying to do that at all. I just want to make sure we had that understood.

Senator COCHRAN. Do you have any other questions of this panel?

Senator GLENN. No, that is all. Thank you.

Senator COCHRAN. We appreciate very much your being here and providing testimony to our hearing. Thank you very much.

Mr. TRIVELPIECE. Thank you, Mr. Chairman. Senator Glenn, thank you.

Senator COCHRAN. We have a final panel of experts in radiation epidemiology. We ask that they come forward at this time.

The panel includes Dr. Roy Shore, who is associate professor of the Department of Environmental Medicine at the Laboratory of Biostatistics in Epidemiology, New York University Medical Center; Dr. Ethel Gilbert, who is principal investigator at the Hanford study; and Dr. William Nicholson of the Department of Community Medicine, Mount Sinai School of Medicine, New York.

We thank you very much for being here today and for agreeing to join us in this hearing and present testimony concerning the issues raised in the introduction of S. 525, introduced by Senator Glenn.

We have copies of your statements. We appreciate those, and we will include them in the record in their entirety. If you could make some summary comments or highlight your written statements, that would be appreciated. Let's begin Dr. Shore.

TESTIMONY OF ROY SHORE, PH.D., DEPARTMENT OF ENVIRONMENTAL MEDICINE, NEW YORK UNIVERSITY MEDICAL CENTERS;[1] ETHEL GILBERT, PH.D., EPIDEMIOLOGIST, RICHLAND, WA;[2] AND WILLIAM NICHOLSON, M.D. MOUNT SINAI SCHOOL OF MEDICINE, NEW YORK, NY[3]

Mr. SHORE. Thank you, Senator Cochran and members of your subcommittee, for this opportunity for me to give my perceptions of the DOE epidemiology program. My specialization is radiation epidemiology, and although I, myself, have never applied for a contract or a grant from DOE, I have appreciable contact with the DOE epidemiology program since I have served on the advisory committees for four of the major epidemiology studies which they fund.

I have also served on a research advisory committee to the division of DOE which administers the epidemiology program, and we were given a charge to evaluate the epidemiology program and recommend improvements in it. A copy of our report has been submitted to this subcommittee as an appendix to Dr. Trivelpiece's testimony.

[1] Mr. Shore's prepared statement appears on p. 219.
[2] Mr. Gilbert's prepared statement appears on p. 223.
[3] Mr. Nicholson's prepared statement appears on p. 225.

I would like to emphasize certain points today. The first is that the DOE epidemiology studies have had repeated review by outside groups of peers, probably with greater frequency than many other epiodemiologic studies. The members of the various review committees have included internationally recognized experts in cancer epidemiology and radiation epidemiology, in biostatistics, genetics, radiation biology, radiation dosimetry and industrial hygiene.

These peer review groups have closely scrutinized the methodologies, the results and the study plans of the DOE epidemiologic researchers.

We have, over the course of time, made various recommendations or suggestions to those researchers and have found that the study invetigators have welcomed and used those suggestions. I think it is fair to say that they are interested in doing the best studies they can.

My second point is that the methodologies used in these studies have been sound. The analyses have been performed by well-trained statisticians, and without going into detail, I will just summarize and say that I think it is doubtful that the studies would be conducted significantly better by any other organization.

Third, a transfer of the DOE epidemiology program to another agency would probably mean a delay in completing the studies and would increase their cost, since the new group of investigators would have to spend considerable time learning all the intricacies of the data collection and other phases of the studies. It is also unlikely that another agency would have available the same degree of expertise in radiation dosimetry that the DOE has.

This lag might slow the studies down further or it might exacerbate the already existing limitations in the historical dosimetric estimates that are available.

Fourth, the fact that the DOE has continued to perform such long-term, costly studies is a clear indication that they have the concern for the health of their workers and a commitment to monitor that health. I think it is doubtful that another agency of the Government would have such a sustained commitment to the DOE workers.

There is a real danger that another agency might pursue the studies with zest for a few years then let the program languish if the investigators did not continue to find new and interesting results. I believe a long-term commitment of DOE through the epidemiology program is a compelling argument for keeping it in DOE.

Thank you.

Senator COCHRAN. Thank you, Dr. Shore.

Dr. Gilbert.

Dr. GILBERT. As a scientist who is currently involved in the Department of Energy's sponsored epidemiology study, I appreciate the opportunity to appear before you today. I will try to describe the scientific environment in which I work and to show that it is one that rewards competence and objectivity and strongly discourages anything short of that. To a large extent, I believe that the views that I will be expressing are shared by other scientists with responsibilities for epidemiological studies currently funded by the Department of Energy.

My scientific discipline is biostatistics. I have a Ph.D. in that field. For the past 10 years, I have been responsible for the analysis of data on workers at the Hanford nuclear facility. I am not employed by the Department of Energy, but by Battelle, which is a private research company which performs contract research for several organizations, including a major contract with the Department of Energy.

No one at DOE has ever tried to influence in any way the results of the Hanford study. In fact, my contracts with personnel at DOE are quite limited. With regard to Battelle management, there has never been the slightest hint or suggestion that anything other than good scientific judgment should play a role in determining the methods that are used to analyze the Hanford data or the manner in which findings are reported. The concern of Battelle management, as I preceive it, is that the analysis of the Hanford workers study be conducted competently and in a manner that can be defended to the larger scientific community.

Our study is subject to a very strong review process. First, several papers describing both the results and the analyses of the Hanford data and the statistical methods used to attain them have been published in respected professional journals. That means that first, the papers were subject to reviews by referees appointed by Battelle, and it also means that the results and methods are available for anyone to examine.

We have a permanent advisory committee that has met five times since 1980 to review our project. In addition, our study has been reviewed by other special committees. The members of these review committees have included permanent experts in the fields of statistics, epidemiology and health physics and have come from universities and the National Cancer Institute.

Personally, I regard it as very important to have any work evaluated by other scientists and to exchange ideas with others who may have different perspectives. I attend scientific professional meetings in the field of physics and epidemiology, some of which are focused on specific problems and the health effects of radiation.

I have made numerous presentations at these meetings, and I have also made many presentations to lay audiences. I am regularly exposed to many points of view and regularly called upon to defend our findings both on a scientific basis and in a manner that nonscientists can understand.

I think it is important to maintain continuity of studies such as the Hanford workers study; such studies not only require management of very large amounts of data, but also pose unique statistical problems. The capabilities for conducting such studies cannot be developed in a short period to time. In the years that I have been working on the Hanford study, my colleagues and I have devoted considerable effort to developing and implementing statistical procedures that provide for assessment of risk that are as sensitive and free from bias as possible. An early publication describing our basic methodology received an award from the American Statistical Association.

We have a number of other publications dealing with various specific methodological issues that arise in these studies. I might note also that we do have access to the source documents which

constitute the raw data, and on many occasions we have consulted these documents to obtain a better understanding of these data. As a scientist, it is important to me to have my work published in the best journals and to win the respect to the larger scientific community.

That means that I have a very strong incentive to produce work that is both objective and competent and absolutely no incentive to do othewise.

I feel that I have a strong responsibility to make every effort to see that the Hanford workers data are analyzed, using the most sensitive and unbiased methods available, and to see that the findings are interpreted and reported in an appropriate manner. I believe that this sense of responsibility is shared by other researchers working on epidemiological studies funded by the Department of Energy.

Thank you for considering my point of view, and I would be glad to respond to questions later.

Senator COCHRAN. Thank you, Dr. Gilbert.

Dr. Nicholson.

Dr. NICHOLSON. Thank you, Mr. Chairman.

I appreciate very much this opportunity to speak before you. My name is William J. Nicholson, and I am an associate director of the Division of Occupational and Environmental Medicine and professor of community medicine at Mt. Sinai School of Medicine, where I have conducted epidemiological research since 1969.

This statement is offered jointly by myself and Dr. Phil Landrigan, the director of the division, and is submitted by us as individuals and not on behalf of the institution. Dr. Landrigan is currently abroad and, unfortunately, unable to appear before you.

I would like to briefly speak about three issues relating to epidemiological research on radiation effects. Radiation has been one of the best studied of carcinogenic and genotoxic agents in the environment. Nevertheless, our understanding of its effects is still incomplete. Disagreements exist as to the appropriate modeling on health effects, on particular exposures, and on estimating cancer risks from exposures in the general environment. Even exposures to substantial quantities of radiation lead to disagreement among respected scientists.

Estimates of the doubling doses for cancer in different sciences range over an order of magnitude. The Department of Energy has, indeed, conducted many studies that are very valuable in this area. Nevertheless, I feel they have not exploited the full potential for such research in the past, and it is evident that considerably more research should be done and can be done. I think it can better be done under the auspices of the Department of Health and Human Services with additional personnel brought to bear upon the problems.

The conduct of such research under HHS would carry the advantage of being able to utilize their grant program to streamline research proposals by academic investigators that would undergo the critical peer review system of the Division of Research Grants. Further, greater access to populations employed in the industry by academic and NIH scientists could obviously increase the potential for obtaining radiation effects.

Finally, the result of such long-term low-level investigations by scientists outside the nuclear industry will be more easily accepted by all individuals concerned with radiation health effects.

I am not suggesting that DOE scientists or DOE-sponsored research is not objective. I am saying that the health effects of radiation can be an emotional issue to many affected people, and it is important that radiation reseach, in addition to being objective, be perceived to be as objective as possible. This perception is much better achieved with HHS-supported research than with DOE research.

Second, an essential element in the use of hazardous materials is a superior health and safety program for the workers therein employed. There must be adequate medical facilities, surveillance programs appropriate to the work and exposure circumstances, and when warranted, epidemiological studies of populations or exposures of concern.

The maintenance of health facilities and plant monitoring should be conducted by the plant facility personnel. However, it is important that such medical monitoring programs be reviewed by outside, independent agencies which also can undertake epidemiological studies of worker populations to establish the presence or absence of health effects. This is just an elementary check and balance that should be present whenever lives are at stake. This is no more than exists in the private sector.

In the case of epidemiological studies of DOE workers and the use of existing monitoring programs, this can best be done by an agency at HHS, such as NIOSH. In principle, this can be done with the concurrence of DOE. However, in the past, DOE has been less than cooperative in such studies. I will illustrate two in particular. In February 1983, NIOSH received a request from the International Association of Machinists and Aerospace Workers to conduct a health hazard evaluation at the Feed Materials Production Center in Fernald, OH. It has gained a certain notoriety in this hearing already.

Six months of negotiations were required by NIOSH before an initial visit and tour of the facilities were allowed in October 1983. At that time, NIOSH requested health and safety reports and access to medical and environmental records of the plants. They were informed that delays would occur because of the requirements of the Privacy Act.

However, it was not until 1984 that DOE proposed to give NIOSH such medical records. Access was finally granted in March 1985. This allowed a study of approximately 150 workers to be undertaken in September, 2½ years after the initial request for an investigation.

Similar delays were encountered in a request by the Oil, Chemical and Atomic Workers Union at the Goodyear Atomic Corp. in Piketon, OH, in which a request for health hazard evaluation through radiation from urinayl fluoride was made in 1979. It was not until March 1982 that NIOSH was able to undertake the study in that facility.

Finally, if a substantial accident occurs within a nuclear facility, either private or under DOE control, the need for completely independent evaluation of the resulting hazard is especially important.

At the time of any crisis, initial reactions of those involved are defensive, and an unbiased evaluation from members of the agency withing which the accident occurred may not be immediately forthcoming.

Hence, outside evaluation by individuals from a different agency having no responsibility to those that had responsibility for the accident facility is clearly beneficial.

Here, if such a capability existed within HHS, the availability of a skilled team of investigators of rapid utilization would be especially important. In such studies of accidents, we are largely dealing with epidemiological studies that would be clinical in nature. That is long term. Here, the ready access by HHS people to individuals knowledgeable in various clinical aspects of whatever the hazard might be is an important benefit.

I would just want to make one comment on the bill, which specifies that HHS authority be vested in the Centers for Disease Control. We would suggest that the authority to conduct the epidemiological studies of radiation effects among workers be specifically vested in NIOSH, the agency within CDC which now has that responsibility.

This will necessarily lead to a substantial increase in the professional and support staff of NIOSH. Clearly, provisions will have to be made to have this coverage. Comments have been made previously about the difficulties that might be encountered in the transition of the transfer of authority from DOE to HHS.

In the studies that are currently underway, I think common sense can easily overcome many of these objections. It is not an issue of totally not including such studies. With such common sense, and in order to transfer, what would be affected is the ultimate goal, that of having the authority to undertake these studies with HHS, at which time, then, clearly, the unbiased and appropriate studies can be undertaken in cooperation with all individuals involved.

In conclusion, we believe that the transfer of authority to conduct epidemiological studies at HHS has clear advantages. It will increase the number of reasearch scientists active in radiation health effects and thus the quality of information.

It will be providing a more accepted and efficient mechanism for investigation of hazards to current nuclear workers and to others exposed to radiation in other circumstances.

Thank you.

Senator COCHRAN. Dr. Nicholson, would you agree that DOE epidemiology studies receive a great deal of attention and review by members of the scientific community?

Dr. NICHOLSON. Yes; we do.

Senator COCHRAN. Isn't it true that we could expect to hear from members of the scientific community who had doubts about the validity and accuracy of findings made by these studies? Wouldn't we expect that, if there were such?

Dr. NICHOLSON. If there were preceived and evident problems with such studies, the review process is one that would pick those up.

The point I had been making was that in addition to such review, I believe there are opportunities for further studies that

have been not fully exploited. In many circumstances, the issue of epidemiological research is not on the conduct of good research, but the ability to do that particular research in particular circumstances. That is an issue that doesn't quite have the peer review process that may be in place now as effective as it might be in the case of an outside agency looking for opportunities.

Senator COCHRAN. Dr. Shore, you mentioned that you served on advisory committees for DOE studies. Do these committees include a wide range of viewpoints and experience, or would you say these are folks who are chosen who are going to support the nuclear industry? How would you characterize other members of the committees?

Mr. SHORE. I would say they are drawn from a broad range of experts in various aspects having to do with radiation who, by and large, are not employed by DOE; don't have any particular vested interest. They find their funding from the sources. They have done their research independently of that.

Senator COCHRAN. Would it be fair to say that your judgment of the quality of the work is that it does reflect competence? What is your opinion of the quality of the studies that you have seen performed under the sponsorship of DOE?

Mr. SHORE. I think that compared to the broad range of epidemiologic studies, that they compare quite favorably, and some of them have been truly excellent. Others, good to excellent. You can get shades of grading, but I think overall, they fare quite well.

Senator COCHRAN. Dr. Gilbert, you mentioned the motivation to be respected by others in the scientific community on the basis of the quality of work done, and that impresses me. I might ask you if you are aware of any instances where investigators or researchers were directed to alter their findings of make any particular findings or Department of Energy officials.

Mr. GILBERT. I am not aware of any such incidents.

Senator COCHRAN. In your opinion. Does the fact that DOE funds the studies give any reason to suspect the quality of the research or the validity of the findings of these efforts?

Mr. GILBERT. Well, I know I would not do my job any differently. It would not depend on the source of the funding, and I don't think it would for most scientists.

Senator COCHRAN. Are you familiar with the research on Hanford workers conducted by Drs. Mancuso, Stewart, and others?

Mr. GILBERT. Yes.

Senator COCHRAN. If you are, would you comment for us on the validity of their conclusions?

Mr. GILBERT. I am very familiar with their research. To adequately address the problems of the research, we would be here for hours, but I will spare you that and try to make just a few brief comments.

First of all, their work has been criticized in print by a large number of scientists, many with no associations with the Department of Energy. They have done many different analyses. Most of the written critiques concern their early work. They have updated these findings, but their updated analyses also suffer from problems which we have pointed out, and others in the scientific community have not endorsed their recent work.

The Hanford data have also been analyzed by a number of scientists, including a group of four, two from Harvard, one from the National Cancer Institute, and one from the National Academy of Sciences. They were analyzed by Dr. Sanders, who was associated with Dr. Mancuso for many years, and by a group at the National Radiologic Protection Board in Great Britain. That is, perhaps, particularly relevant, because this group had absolutely no U.S. funding and no motivation to come up with any particular result.

These results, these other analyses have all supported our own conclusions. None have supported the claims of Mancuso, Stewart, and Neal.

Senator COCHRAN. Thank you very much.

Senator Glenn.

Senator GLENN. I think this idea of who criticized whose reports here is one we can get into in the scientific community and prove anything by almost anybody's criticisms. The Mancuso affair was well publicized, of course, and that was some years ago; that was 1977. I guess it was.

But on the other hand, is it not true that the Center for Disease Control is very critical of a DOE report on Savannah River? Are you familiar with that one?

Mr. GILBERT. I am not thoroughly familiar with it. I can't acknowledge what you are saying.

Senator GLENN. I think who supports what report here is something, the point being that DOE reports have not been without their critics also is the point that I would make.

Dr. Nicholson, I was interested in your comment about CDC versus NIOSH. Could you expand a little bit on that? Then I would like to have your comments on if we did go this route, what would be the best agency to do some of this, CDC, or NIOSH or what? Would you expand on your comment a little?

Dr. NICHOLSON. I made the specific comment with respect to NIOSH, because it is now obviously the agency that is most intimately involved in worker health research. It has a very extensive industrial hygiene staff, a staff of epidemiologists concerned with the study of health effects in the workplace. As was mentioned earlier today, when one would look at health effects in the nuclear industry, there would be exposures to agents other than radiation and the combination of the exposures and their evaluation will be an important aspect of this.

The existing skills of that institute in the evaluation of these other workplace exposures, I think, is especially important and would be useful, and thus the suggestion for having it vested specifically in NIOSH was made.

Senator GLENN. In your experience, Dr. Gilbert, who would be the most capable in this area, NIOSH or CDC?

Mr. GILBERT. I think NIOSH is within CDC.

Senator GLENN. CDC does other epidemiological studies apart from NIOSH.

Mr. GILBERT. I really couldn't make that judgment.

Senator GLENN. Dr. Shore, do you have a comment?

Mr. SHORE. With regard to the occupational aspects, as he mentioned, in industrial hygiene, clearly, NIOSH has more expertise, to my knowledge, anyway. With regard to radiation, neither of the

agencies has all that much experience in radiation epidemiology, though they do have a certain amount. So that if radiation is the main thrust, I would judge that neither of them would be preferred over DOE.

Dr. NICHOLSON. Can I just make one point? It is true that certainly, the radiation epidemiological capabilities of NIOSH or CDC would have to be substantially expanded. That is evident. NIOSH has been involved in radiation studies. They are the agency that conducted the studies, and its predecessor, of the Colorado uranium mines. It is one of the more extensive studies in that area. They have done a large number of lesser-sized studies of particular exposure circumstances to radiation, but certainly, there is the need for an expansion of the personnel and capabilities.

Senator GLENN. Thank you, Mr. Chairman.

Senator COCHRAN. Let me thank each one of you again for being with us this morning and helping us in the conduct of our hearing. We thank you for your presence and your contribution. This concludes our hearing. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 12:25 p.m., the subcommittee was recessed, to reconvene subject to the call of the Chair.]

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

99TH CONGRESS
1ST SESSION

S. 525

To transfer to the Secretary of Health and Human Services the authority of the Secretary of Energy to conduct epidemiological studies of the effects of radiation, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 27 (legislative day, FEBRUARY 18), 1985

Mr. GLENN introduced the following bill; which was read twice and referred to the Committee on Governmental Affairs

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A BILL

To transfer to the Secretary of Health and Human Services the authority of the Secretary of Energy to conduct epidemiological studies of the effects of radiation, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Radiation Reorganization Act of 1985".

SEC. 2. The Congress makes the following findings:

(1) After many years of study there remain unresolved questions about the human health effects of radiation exposure from many sources such as nuclear

bomb tests, the manufacture of nuclear weapons, residing near nuclear production facilities, nuclear power plants, and radioactive wastes, and the medical uses of nuclear materials.

(2) The epidemiology of radiation-caused injury and disease, including cancer, birth defects, and genetic damage, must be examined and understood in relation to experimental studies in animals.

(3) Public health authorities must be able to direct research efforts so that effective means of protecting the public against dangerous exposure can be developed and achieved.

(4) The Secretary of Energy's responsibility for production of nuclear materials and nuclear weapons conflicts with the responsibility of the Secretary under the Energy Reorganization Act of 1974 to study the health impacts of activities of the Department of Energy and such conflict has created public doubt as to the integrity of the health impact studies of the Secretary.

SEC. 2. (a) There is transferred to the Secretary of Health and Human Services the authority of the Secretary of Energy to conduct, under section 103 of the Energy Reorganization Act of 1974 and any other law, epidemiological studies of the effects of radiation. With respect to the author-

ity to conduct studies of the health effects of radiation in places of employment on individuals employed in such places, the Secretary shall exercise such authority through the Director of the Centers for Disease Control. In carrying out the function transferred by this subsection, the Secretary shall consult with the Director of the National Cancer Institute, the Director of the National Institute of Environmental Health Sciences, the Director of the National Institute for Occupational Safety and Health, and the Director of the Center for Devices and Radiological Health.

(b)(1) There are transferred to the Secretary of Health and Human Services—

(A) the personnel employed,

(B) the property and records now being used or held,

(C) the obligations and commitments made, and

(D) the unexpended balances of appropriations, allocations, and other funds available (or to be made available) for use,

by the Secretary of Energy in connection with the function transferred by subsection (a).

(2) The Director of the Office of Management and Budget, at such time or times as the Director shall provide, shall make such determinations as may be necessary with regard to the functions transferred by subsection (a), and

make such additional incidental dispositions of personnel, assets, liabilities, grants, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds held, used, arising from, available to, or to be made available in connection with such function as may be necessary to carry out the transfer.

SEC. 3. (a) To advise the Secretary of Health and Human Services in carrying out the function transferred by section 2(a) there is established an advisory panel. The panel shall consist of seven members appointed by the Secretary. The Secretary shall make appointments to the panel so that the membership of the panel will represent individuals who are expert in the conduct of epidemiological studies of the health effects of radiation, individuals who represent public interest groups concerned about the health effects of radiation, and public health officials who deal with such health effects.

(b)(1) Except as provided in paragraph (2), members of the panel shall (A) each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the panel, and (B) while away from their homes or regular places of business and while serving in the business of the panel, be entitled to receive transportation

expenses as prescribed by section 5703 of title 5, United States Code.

(2) Members of the panel who are full-time officers or employees of the United States shall receive no additional pay, allowances, or benefits by reason of their service on the panel.

(c) The Secretary shall provide such administrative support services for the panel as it may request.

ENVIRONMENTAL POLICY INSTITUTE

STATEMENT OF ROBERT ALVAREZ

BEFORE

THE U.S. SENATE GOVERNMENT AFFAIRS

SUBCOMMITTEE

ON

ENERGY, NUCLEAR PROLIFERATION, AND

GOVERNMENT PROCESSES

REGARDING

S.525 - A BILL WHICH WOULD TRANSFER AUTHORITY OF THE U.S. DEPARTMENT OF ENERGY TO CONDUCT RADIATION EPIDEMIOLOGICAL RESEARCH TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.

JUNE 17, 1986

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SUMMARY AND CONCLUSIONS

The Environmental Policy Institute (EPI) strongly supports enactment of H.R. 1287 - legislation which would transfer authority to conduct radiation epidemiological research from the Department of Energy (DOE) to the Department of Health and Human Services (HHS). There are several compelling reasons why this legislation is necessary.

First, the control excercized by DOE over this sensitive area of research has compromised scientific objectivity to the point where American citizens no longer trust federal agencies to protect them from civilian and military nuclear activities. The source of this mistrust is a legitimate concern that the health of thousands of people who live near or work in nuclear facilities may be in jeopardy. DOE's interest in radiation health effects stems from their primary missions to produce nuclear weapons and promote nuclear energy. This fundamental conflict-of-interest between nuclear promotion and public health protection has been well documented for the past several years by extensive Congressional oversight hearings, federal court decisions and executive agency investigations.

Second, for more than 40 years hundreds of thousands of military and civilian personnel and people living near federal nuclear installations have been exposed to levels of ionizing radiation from nuclear weapons development which are being shown to be dangerous. The Department of Energy has made it very clear that their number one priority in the area of radiation policy is to fight every single claim filed by these people for radiation injury, regardless of the scientific merit of DOE's position. Having DOE control research which will determine the outcome of such claims is a clear violation of basic principals of scientific freedom and responsibility, which can only lead further public opposition to nuclear acitvities.

Third, the DOE's installed industrial capacity to manufacture nuclear weapons is in excess of thirty years of age. Although changes in nuclear health and safety standards relative to commercial nuclear power plants have undergone steady change, DOE standards for its facilities have not changed significantly for more than 25 years. Thus, studies which suggest that DOE nuclear facilities pose unacceptable radiation health risks to workers and members of the public are percieved by DOE as threats to their primary mission. In essence, DOE's bureacractic self-interest has dangerously blurred distinctions between national security and protecting the health of American citizens from their nuclear activities. In a candid but disturbing comment on the priorities of DOE, Dr. William Loewe , a radiation health effects expert at DOE's Livermore National Laboratory stated recently, "there are tens of billions of dollars to be spent in the commercial and nuclear defense industries if protection standards were to be changed." Loewe succinctly characterizes the kind of pressure that compromises objective research funded and supervised by the Energy Department.

DOE's control over radiation epidemiological studies reflects and inherent bias which has taken the forms of misleading statistics and crude analytical methods which are then used to support spurious public claims about the lack of health risks at DOE nuclear installations. Commensurate with these distortions, the DOE and its contractors have supressed studies which are unfavorable to official views and have selectively eliminated high risk groups from study.

DOE officials have publically attacked independant scientists, while internally acknowledging that the methods used by these same scientists are superior.

At the heart of DOE's conflict -of-interest is it's policy on epidamiologic data utilization. Rsearchers analyzing DOE worker data are not allowe direct access to source data and are therefore not in the posision to verify the

data's accuracy and completeness. They are also not in the position to prevent destruction of records which may prove valuable for research but also may be damaging to DOE's efforts to fend off compensation claims. Officials at DOE's Oak Ridge Associated Universities* confirmed last November that they did shred and burn 21 out of 41 filing cabinets of medical records of Oak Ridge residents, which were set aside by the original principal investigator of DOE's occupational health and mortality studies. Moreover DOE and ORAU were aware that these records were listed in an inventory of data by the original principal investigator as "source data." Whether or not these records were destroyed deliberately or out of carelessness does not change the damage done, relative to the epidemiological studies of Oak Ridge people and the ability of residents of Oak Ridge to obtain compensation.

Although DOE claims that their data utilization policy is designed to comply with the Privacy Act, such restrictions are not placed on investigators at public health agencies like the National Institute for Occupational Safety and Health (NIOSH). The Subcommittee on Energy, Nuclear Proliferation and Government Processes should ask the General Accounting Office (GAO) to investigate the extent to which data in the possession of DOE or its contractors has been destroyed or is being improperly assembled.

Removal of the DOE from funding and supervision of epidemiological research is necessary for the development of objective radiation protection policies. This step is vital if the federal nuclear program is to meet the same health and safety standards as those required for the private nuclear program. Not only will this legislation help restore credibility of the federal government in protecting its citizens from nuclear activities, it will perform a service for both sides of the radiation health effects debate.

* ORAU is a government-owned-contract-operated facility.

BACKGROUND

Mr. Chairman and Members of the Committee, I am Robert Alvarez, Director of the Nuclear Power and Weapons Project of the Environmental Policy Institute (EPI). EPI is a non-profit public interest research, education and public advocacy organization which addresses public policies on national and international security, public health, agriculture, natural resources and energy. I am pleased and grateful for the opportunity to present EPI's views relative to H.R. 1287 - legislation which would transfer the responsibility for radioepidemiological research from the Department of Energy (DOE) to the Department of Health and Human Services (HHS). EPI strongly supports this measure.

Efforts to break-up the monopoly control held by the federal nuclear weapons bureacracy over radiation health effects research have their origins in the controversy over the public health impacts of federal and commercial nuclear activities. It is a controversy which has been raging for over 30 years. To a large extent, H.R. 1287 is a result of extensive Congressional interest in the long-term effects of human exposure to ionizing radiation which began in 1976, when the first Congressional Seminar on low-level ionizing radiation was organized by EPI. 17 Investigations and hearings by several Congressional committees held between 1977 and 1981, not only broadened the public record on the scientific debate, but moreover, revealed serious deficiencies in federal radiation protection and research programs. This series of Congressional inquiries documented: (a) a long-standing pattern of federal misrepresentation and distortion of radiation hazards; (b) the supression of research damaging to official views; (c) the unwarranted attack on independent researchers and the severing of their funds after they reported findings indicating greater than expected health risks from nuclear activities.

Most importantly, these Congressional oversight hearings revealed the magnitude of the potential public health legacy of the past four decades of civilian and military nuclear activities. 2/ 3/ 4/ 5/ 6/ We now know that some 250,000 military personnel and a similar number of civilian personnel took part in atmospheric nuclear weapons explosions at the Nevada Test Site and the South Pacific islands. About 600,000 radiation workers have been employed in the federal nuclear program since the 1940s. Serious accidents involving large releases of radioactivity from federal nuclear facilities have taken place. Global fallout from atmospheric weapons explosions have also taken their toll. Although it is impossible to precisely quantify the total human health damage from atmospheric weapons tests, a dose estimate of 540 million person-rems* has been made by the United National Scientific Committee on the Effects of Atomic Radiation (UNSCEAR 1982). This dose is applied to the current range of dose/effect coefficients is expected to give rise to excess cancers world-wide numbering between 213,000 and 3.5 million. 7/ A 1979 Nuclear Regulatory Commission staff analysis calculates that as many as 170,000 people will suffer adverse genetic damage from weapons fallout by the end of the century. 8/ The adverse health effects of nuclear weapons fallout on a more local scale have been found to be convincing enough for the Federal District Court in Salt Lake City,Utah to levy damages against the federal government to compensate several residents living near the Nevada Test Site during the open air testing program. The court also made note of the fact that the government was clearly negligent and falsely represented the hazards of radiation to citizens living near NTS at the time. 9/

* The term "person-rem" is used to express a collective radiation dose where the dose is averaged over the population exposed. For instance, a million person-rems could mean that one million people each recieved one rem, or 100,000 people each recieved ten rem etc.

Much of this information was already known by 1979, when an Interagency Task Force on Ionizing Radiation was convened by President Carter under the Chairmanship of the Department of Health, Education and Welfare (now HHS). In 1980, after exhaustive review of the situation, the Task Force issued a series of recommendations. The most important recommendations to these deliberations today deals with federal radiation health effects research. The Task Force noted that the U.S. Department of Energy (DOE) funds over 60 percent of all radiation health effects research. In FY 1986 the DOE has been appropriated $184. 7 million for biological and environmental health research. Of that amount about $24.2 million is to go for epidemiological research into the long-range effects of ionizing radiation. 10/

According to the FY 1986 Budget Justification by DOE:

> "Investigations included in this program provide basic data for use in developing and refining radiation protection standards, as well as assuring the health and safety of DOE workers, employees of its contractors and the general public." 11/

Without question, DOE's primary interest in radiation and human health stems from its missions to provide nuclear weapons of the U.S. arsenal and to promote nuclear energy as a commercial buisness. Not even in the most remote sense is the DOE a public health agency. The Interagency Task Force recommended that DOE's radiation health effects research program be transfered to a federal public health agency. 12/

Although Congress enacted legislation in 1978 giving the Department of Health and Human Services authority to coordinate federal radiation health research, the basic conflict-of-interest remains. By not effectively controlling the funding for radiation health research, the Interagency Committee on

Radiation Research (ICRR) is mere window dressing for the monopoly control that the nuclear weapons bureaucracy has over radiation and public health policy in this country. That is the crux of the problem.

Radiation epidemiological research under control by the DOE dictates the terms of public health policy not only for the manufacture of nuclear weapons but also commercial nuclear energy, industrial applications of radiation and most significantly the medical uses of radiation. This fact was made very clear at a recent meeting of the Baltimore/ Washington Chapter of the Health Physics Society on September 19th of ~~this~~ LAST year by Mr. Brian Siebert, a DOE attorney affiliated with the White House Coordinating Committee on Ionizing Radiation Policy (CCIRP). Mr. Siebert in his talk entitled "Radiation Under Attack: Strategy of the Offense and Defense", stated that the administration's "party line" was that if standards were tightened as a result of losses due to legal claims, this could curtail the production of nuclear weapons, commercial nuclear power development and the uses of radiation in medicine. The implication of Mr. Seibert's speech was that the Health Physics Society has a responsibility to fight these radiation compensation cases. Thus it comes as no surprise that DOE and the Justice Department has been sponsoring seminars at the various chapters of the Health Physics Society around the country on how to fight legal claims for radiation injury. DOE's conflict-of-interest is no more apparent than these blatant efforts using tax payer's money to indoctrinate the very profession responsible for radiation health and safety so that the political goal of the nuclear weapons program can be met regardless of the scientific merit of their position.

But what about those people who may have suffered as a result of living near or working in a nuclear facility? What about the medical patient who may suffer as a result of the excessive use of radiation? These questions are being lost in the "glacial bureacratic drift" of the federal nuclear program, which is soley interested in it's primary missions of nuclear promotion.

THE DOE's RADIATION EPIDEMIOLOGICAL RESEARCH

H.R. 5971 would affect several studies now being funded by DOE. They include:

- The Life Span Study of the Japanese Atomic Bomb Survivors;
- studies of U.S. radium dial painters who ingested radium in the course of their work;
- studies of New Mexico uranium miners exposed to radon gases;
- studies of Department of Energy contract employees and employees of DOD contractors at nuclear navy shipyards;

Perhaps the most important studies that will impact on radiation standards for millions of Americans are those dealing with the DOE contract nuclear workers. In the fall of 1977, a study published in the Health Physics Journal ignited a firestorm of debate over the cancer risks of low-level ionizing radiation. The outcome of this debate has important ramifications for civilian and military activities.

At the center of this debate is a 36-year follow-up of some 30,000 workers at the Energy Department's Hanford Plutonium Works in eastern Washington performed by Drs. Thomas F. Mancuso, Alice Stewart and George Kneale. In 1977 Mancuso, Stewart and Kneale (MSK) raported an association between radiation exposure and excess deaths from cancer of the bone-marrow

pancreas, and lung. Moreover, the risk of dying from radiation-induced cancer at Hanford appears to be 10 to 20 times greater than current protection standards assume.

Mancuso's funds were severed by the DOE and unsucessful attempts were made to confiscate his data. Several papers sponsored by DOE and the Nuclear Regulatory Commission were generated without giving Dr. Mancuso the benefit to see them and issue a reply. The contract originally held by Mancuso was transfered to Oak Ridge Associated Universities (ORAU), Battelle Northwest Laboratory (BNWL) and Los Alamos National Laboratory (LANL).

The importance of the Hanford Study by Mancuso and his colleagues is that it has provided for the first time evidence of harm at levels of radiation exposure which are relatively low and which were individually measured. The current basis for radiation standards are studies of people exposed to a single high-dose of radiation (ie the Japanese A-bomb survivors) where the risks of low-level radiation are extrapolated.

Although much has been reported about the political controversy surrounding the termination of Dr. Mancuso's contract, the public and the scientific community in general know very little about the scientific debate over occupational radiation health risks that has been raging for the past eight years. Despite the continued claims by DOE and their researchers that Mancuso et al have been discredited, several papers by MSK have been subsequently published in refereed scientific journals. Mancuso et al have not only answered the initial wave of criticisms but they have also reported other important findings. 13/ 14/15/ 16/ 17/ 18/ 19/

Perhaps the most important question to be asked about the viability of the Hanford study of Mancuso, Stewart and Kneale is :What are present holders of DOE contracts finding in the data that Mancuso helped assemble on about 600,000

radiation workers at several DOE sites?

FINDINGS OF INCREASED CANCER AND NON CANCER RATES AMONG DOE NUCLEAR WORKERS

In the fall of 1984, the Environmental Policy Institute released official reports indicating that DOE nuclear workers at several locations are experiencing greater than expected risks of dying from malignant cancers and certain non-malignant diseases. Much of this information was outlined in a May 1984 Epidemiological Project Summary of studies funded by DOE under contract with ORAU and the University of North Carolina (UNC). Eight out of twelve populations under study were found to have excess cancer death rates -- most of which were described as "significant."

Additional documents obtained through Congressional requests and a Freedom of Information Act request indicate that in all twelve populations of DOE nuclear workers are experiencing significant health problems. They include:

1. A 36 year follow-up of 30,000 workers at DOE's Hanford Plutonium Works in eastern Washington has reported an association between excess deaths from cancer of the bone marrow, pancreas and lung. Radiation cancer risks were shown to be 10 to 20 times greater than current protection standards assume.

2. A study based on 8,737 white male workers at DOE's Oak Ridge National Laboratory in Tennessee indicates that maintenance and engineering workers at the Laboratory have high risks of dying from leukemia. Leukemia mortality risks were shown to be associated with duration of employment and exposure to external radiation.

3. A study based on over 16,000 workers at DOE's Oak Ridge National Laboratory found that workers hired before 1949 who were under 39 years of age at date of hire and were exposed to external radiation have more than a nine fold risk of dying from all cancers when compared to other workers at the laboratory.

4. Studies of some 7,112 white male workers at the Rocky Flats nuclear weapons plant near Denver, Colorado show increased risks of dying from brain tumors and contracting skin cancer.

5. A study of active workers at DOE's Livermore National Laboratory shows a 3 to 4 fold increased risk of contracting malignant skin cancer and a smaller but significant risk of contracting cancer of the salivary glands.

6. A study of workers at DOE's Savannah River Plant near Aiken, South Carolina indicates significant risks of lung cancer and leukemia, particularly leukemia among wage employees.

7. Based on a study of 6,400 white male workers at the Oak Ridge, Tennessee Y-12 weapons plant, the risks of dying from brain tumors and leukemia were found to be over 5 and 10 times respectively.

8. A study of 19,000 women who worked at the Tennessee Eastman Y-12 Plant between 1943-47, has found increased death rates from non-malignant respiratory dosease, cancer of the blood forming organs, brain cancer and cancer of the uterus, cervix and skin.

9. A study of white males who worked at the same Tennessee Eastman facility has established increased risks of dying from lung cancer following exposure to uranium dusts even after smoking was factored in.

10. Workers at DOE's Fernald, Ohio Uranium Feed Materials Production Center show significant risks of dying from gastro-intestinal cancers and were shown to experience excess death rates from fibrosis of the lunf following exposure to uranium dusts.

11. A study of 1,320 white male welders who worked at various Oak Ridge nuclear facilities between 1943 and 1977 show excess death rates from emphysema.

12. A study of 2, 529 white male workers who recieved a total cumulative dose over 5 rem show increased death rates from rectum cancer.

DOE officials and their contractors have publically described these findings as preliminary and inconclusive. A formal written response written by Dr. Robert Goldsmith, the DOE epidemiological research contract officer echos these claims. However, it is difficult to believe that twelve populations of radiation workers where significant increased risks of dying from and/or contracting cancers and non-cancers can be described as insubstantive.

DISTORTION OF RESEARCH BY DOE

Last year, the Review an official publication of the Oak Ridge National Laboratory (ORNL) editorialized:

> "our operations do not threaten the health of people; in fact epidemiological studies indicate that ORNL employees have lower death rates from many diseases, including most cancers, than does the U.S. population as a whole. In addition statistics show that one of the safest places one can be is not at home or on trips but working at ORNL." 20/

Two years earlier on October 19th, 1982, Rockwell International (which operates DOE's Rocky Flats facility) made the same claim in a press release which declared that "Rocky Flats has a healthy workforce." In a later report 21/Rockwell stated that there was "no evidence of increased cancer mortality" among Rocky Flats workers.

Thus, DOE contractors at Oak Ridge National Laboratory and Rocky Flats have proclaimed that these two nuclear facilities pose no danger and moreover are most likely "health farms" for workers. But when the actual studies are examined these statements are blatant distortions of research. As noted earlier in my testimony DOE's studies have found that leukemia and overall cancer death risks are very high among ORNL workers. Brain tumor and malignant skin cancer risks at Rocky Flats are also very high.

DOE contract researchers have also been eager to testify against nuclear workers in a manner which contradicts their own research. For example, Dr. C.C. Lushbaugh, the Principal Investigator between 1976-84 of several studies conducted by ORAU testified before the National Labor Relations Board on behalf of the Aerojet Corporation against workers seeking job reinstatement at a uranium processing facility in Jonesboro, Tenn. According to Lushbaugh the studies he then supervised as of July 1984, "have not caused ... some kind of fibrotic lung disease of emphasema..21/ However, a study of workers at the Fernald, Ohio urnaium processing facility, which Lushbaugh supervised reported several weeks prior to Lushbaugh's testimony before the NLRB that there was "an association between exposure to uranium and the development of non-malignant respiratory disease /fibrosis of the lung/."22/

These and several other examples of DOE's distortion of their worker health studies are contained in a report I authored in June of last year. DOE has yet to issue a reply.

At the heart of DOE's conflict-of-interest is their policy on data utilization. Investigators responsible for studying DOE workers are not allowed to have direct access to source data and therefore have no means to verify its completeness and accuracy. Specifically, researchers analyzing DOE worker data are not provided with personal identifiers. By not having direct access, investigators are not in the position to prevent destruction of records which may prove valuable for research but also may be damaging to DOE's efforts to fend off legal claims. Companies which operate DOE nuclear facilities have the primary responsibility developing and properly preparing DOE worker data. All of this research is then put at the discretion of Oak Ridge Associated Universities (ORAU) a government-owned-contractor-operated facility which predominanantly employs former DOE research and management personnel.

Under this system there are no independent checks over DOE and its contractors who bear liability for radiation claims and at the same time are responsible for screening and processing data which may affect the outcome of such claims. It is like giving the asbestos industry primary responsibility for preparing worker health data for studies which will affect the outcome of their potential liabilities.

In particular, researchers at ORAU have destroyed important medical records, which were assembled by Dr. Mancuso, the principal investigator who held the original contract with DOE from 1964 to 1977. In his final report #13 (see attachment) filed with the DOE in the fall of 1977, Dr. Mancuso listed several types of data including 41 filing cabinets of medical records of Oak Ridge residents that he set aside for future study. On November 21, 1985 the Knoxville News- Sentinel confirmed that ORAU had destroyed 20 of the filing cabinets containing hospital of local illnesses from 1952 to 1961. The other records were prevented from being shredded and burned, after a new epidemiologist put a stop to the destruction.

SUPRESSION OF RESEARCH

In my report, I document two instances where DOE and/or their contractors have supressed research which is unfavorable to official views. The first involves a study done by the E.I. DuPont De Nemours and Co. in 1976 which found increased risks of lung cancer and leukemia among nuclear workers at DOE's Savannah River Plant (SRP). 23/ A copy of this study was forwarded to Dr. Lushbaugh in August of that year. A few days later Lushbaugh's statistician Dr. Tompkins in an August 26, 1976 analysis stated "the apparent risk for leukemia among wage employees appears real." She then urged that " the arguments against this risk being occupationally related need to be expanded." 24/ A second version of her analysis dated August 27th deleted the latter statement. 25/

In the fall of 1983, as a member of a DOE advisory Committee on Epidemiological studies relative to the Savannah River Plant, I asked that all information about the DuPont study be made available to the Committee. DOE not only failed to give us a copy of the Tompkins analysis but also the actual DuPont study which was later obtained through a Congressional request.

The second instance involves a study of 19,000 women who worked at the Tennessee Eastman Y-12 facility between 1943 and 1947. At a public meeting held in the fall of 1984 at an Oak Ridge high school, DOE researchers were asked by Oak Ridge workers if women exposed to radiation are being studied. They were told that women were not being studied mainly because of the difficulty of tracing them because of name changes that result from marriage. However, a year earlier at an "in-House" meeting of DOE health researchers, Dr. Lushbaugh made note that data on 19,000 women at the TEC Y-12 facility had been collected with deaths collected up to 1973. Findings based on these data, according to Lushbaugh, include" an increase in respiratory disease, particularly pneumonia, and a possible increase in lymphopietic cancer,

brain cancer, cancer of the uterus, cervix and skin." [26] When the study was eventually made known to citizens in Oak Ridge by EPI in the spring of 1985, DOE contract researchers conceded that they were studying women but discontinued the study.

USE OF MISLEADING STATISTICS

When EPI released the Epidemiological Project Summaries for ORAU and UNC, Dr. Goldsmith of the DOE issued a reply in the form of "fact sheets." According to Goldsmith, DOE researchers "use standard occupational epidemiological methods. That is, the mortality experience of the entire group of workers is compared to that of the United States general population (SMR study)."

This method has been subject to non-DOE researchers and is even considered by the DOE in internal reports as a "relatively insentitive technique." [27] Dr. Shirley Fry a researcher at ORAU in the spring of this year conceded that the SMR method is "the crudest type of analysis." [28] According to Diane Eisenberg, a University of Wisconsin epidemiologist, whose critique led to a critical review of the DOE's Rocky Flats Worker study in 1983:

> "The hypothesis being tested ... is unsuitable for an occupational hazard investigation. Asking whether workers at Rocky Flats or any industrial plant experience greater mortality than would be expected based on U.S. rates ... generally guarantees a negative finding except for occupational risks of very great magnitude." [29]

The reason that general comparisons of worker death rates with U.S. population statistics is too crude to be of any use is a commonly known phenomena known as the "healthy worker effect." The "healthy worker effect" is commonly attributed to the fact that general population statistics include the invalids, elderly, disabled and hospitalized. Also, employers screen workers for good health prior to and during employment. Thus, industrial

workers have consistantly lower death rates to begin with. That DOE researchers are finding increased cancer death rates with such crude methods, is not only suprising but also an indication that disease risks among DOE workers may be far greater than these studies imply. An example of this can been seen in two studies of workers at the Oak Ridge National Laboratory. The first used a Standardized Mortality Ratio (SMR) method where worker deaths were compared with general population statistics. 30/ This study found significantly lower deaths from all causes except for a 49 percent excess risk of leukemia which was described as "non-statistically significant."

A second study utilized a Case/Control method where all of the cancer deaths among Oak Ridge National Laboratory workers were compared to different sets of matched controls of live workers at the laboratory. When this far more sensitive method was used it was discovered that certain ORNL workers bore risks of dying from all cancers which are over nine times greater than expected. 31/

Another more fundamental misuse of statistics by DOE researchers involves the elimination of cancer cases from the observed categories without making commensurate changes in the expected category. For instance, in his "Fact sheets" Dr. Goldsmith downgrades the importance of leukemia risks at ORNL by stating , "sixteen cases of leukemia were found among white males who worked between 1943-1972 whereas nine were expected, based on U.S. rates. Four of the sixteen were... a type not associated with exposure to radiation. Statiscally, twelve cases are not significantly different than nine." 32/

Dr. Goldsmith implies that 12 leukemia deaths among ORNL workers are the type associated with radiation (ie myeloid), but the expected number of cases for myeloid leukemia is 6.2 not 9. Based on age adjusted rates, this is nearly a twofold excess of leukemia deaths associated with radiation which is statistically significant.

In another instance, Dr. George Voelz and his colleagues at Los Alamos National Laboratory presented a study of 7,112 Rocky Flats workers, where they eliminated 8 out of 16 brain tumor deaths from the observed category without making the necessary adjustments in the expected category. 33/ This study was then used by Rockwell International in a press release which was subsequently reported in newspapers around the country.

ELIMINATING HIGH RISK GROUPS FROM STUDY

Although, DOE has a study of workers at different facilities who have recorded cumulative doses over 5 rems, not all workers at facilities where radiation exposures have been high are being studied. In particular, studies of all workers at the Nevada Test Site and the Idaho National Engineering Laboratory are conspicuous in their absence. The Nevada Test Site workersparticipated in the detonation of atmospheric and underground nuclear weapons tests. They were sent into high radiation zones to retrieve instruments shortly after detonation. They also handled radioactive scrap and bore risks of being in high radiation fallout fields. It is not clear if all of the NTS workers were wearing radiation dosimeters during these tasks.

The NTS workers are an important population to study because they recieved the same kinds of exposures as the military personnel who participated in atmospheric weapons tests. Millions of dollars are being spent to assemble and analyze incomplete data on the military personnel involved in weapons tests. Yet, the data on the NTS workers is far more complete and is in the possession of the Reynolds Electric Co, which operates NTS for the DOE. The NTS can be studied for considerably less cost than the atomic veterans. Perhaps DOE's reluctance to study the NTS workforce stems for concern over liability from claims filed by workers and families of deceased NTS workers.

FOOTNOTES

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5. U.S. Congress, House Committee On Science and Technology, Subcommittee on Oversight and Investiations, Human Total Body Irradiation Program at Oak Ridge, 97th Congress, 1st Session, September 23, 1981.

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STATEMENT OF

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BEFORE THE

SUBCOMMITTEE ON ENERGY, NUCLEAR PROLIFERATION

AND GOVERNMENT PROCESSES

UNITED STATES SENATE

June 17, 1986

P.O. Box 983
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June 17, 1986

The Honorable Thad Cochran
Chairman, Subcommittee on Energy,
Nuclear Proliferation, and
Government Processes
Washington, D.C. 20510

Dear Mr. Chairman:

Thank you for this opportunity to testify concerning Senate Bill 525. This bill, the Radiation Reorganization Act of 1985, would transfer to the Secretary of the Department of Health and Human Services (DHHS) the authority of the Secretary of the Department of Energy (DOE) to conduct epidemiological studies of the effects of radiation. I also thank the Subcommittee for the air fare to come to Washington to present this testimony.

I speak in favor of the proposed legislation for the following reasons:

1. S-525 will result in more effective administration of research programs dealing with the study of radiation effects.

   Each department has a mission to accomplish. An important principle of administration is that responsibilities must be assigned that are consistent with the mission of the department. It is counterproductive to assign responsibilities to a department that are in conflict with that department's mission.

   The principal mission of the DOE is to produce nuclear weapons and nuclear materials. This mission involves working with some very hazardous materials which are known to cause injury. Further, these materials are released offsite from DOE installations to contaminate the environment, and thus present a hazard to the public. The Rocky Flats, Savannah River and Hanford plants and the Nevada Test Site may be used as examples of such DOE installations.

   Over the past years there have been many lawsuits brought by employees against the corporate DOE contractors and the DOE, claiming injury by

exposure to these materials and their radiation. Members of the public have also brought suit, charging injury by materials released offsite from DOE installations. Lawsuits have been brought by landowners against the DOE, claiming that their land has been rendered unsafe for housing due to contamination by radioactive materials released by a DOE facility. Plaintiffs in these lawsuits against the DOE seek key information obtained from radioepidemiological and other studies of radiation effects demonstrating the relationship between exposure to radioactive materials and cancer incidence, genetic injury, reproductive outcome, and nonspecific effects on health such as an increased susceptibility to disease. Their suits are made more difficult by a lack of reliable information concerning such effects, and by the fact that the delayed effects of radiation are more important than the immediate effects.

To assign the responsibility for such studies of the health impact of activities of the DOE to the DOE creates a blatant conflict of interest situation. This conflict of interest is not at all subtle; it is easily perceived by the public. The fact that some of the DOE National Laboratories develop nuclear weapons and some also do health studies does not lead the public to believe that these health studies are independent. The so-called "peer review" system is nothing more than a notorious old-boy network.

The mission of the Department of Health and Human Services (DHHS) on the other hand, is to protect and promote the health of the workers and the public. It makes much better administrative sense to assign the task of epidemiological investigation of radiation-caused injury and disease, such as cancer, birth defects and genetic damage, to that federal department whose principal mission encompasses those activities, despite the poorly-supported protests of losing and receiving departments and their sister agencies.

II. The objections of the DOE to Senate Bill 525 are poorly supported.

While the DOE "strongly opposes" S-525, there is little support for their objections. Mr. Boggs argues that the DOE "historically has been the federal agency charged with responsibility to fund energy-related health effect studies" while its main responsibility is to produce nuclear weapons and nuclear materials. He says the DOE "has supported epidemiologic studies for approximately 40 years as part of an integrated health and environmental research program dealing not just with radiation but also with chemical and other environmental toxins". In this statement he identifies the DOE with its predecessor, the notorious Atomic Energy Commission, and provides an explanation for the slow progress in the development of new information about the effects of radionuclides on health.

The AEC and the DOE record on the health of workers and the public exposed to radioactive materials is well documented in court proceedings and congressional testimony. Recent citations about this record appear

In "Justice Downwind", a book just released by a college dean at the University of Utah. Downwind of the test site, radiation instruments went off the scale in the city streets and official records were later falsified to indicate low readings. Deaths of thousands of sheep in the path of nuclear fallout clouds were dismissed as "malnutrition" by federally-supported scientists in an early court case as they took part in a "fraud perpetrated on the court". U.S. Public Health Service agents burned their clothes and showered to decontaminate themselves, but under AEC orders reassured local people that no precautions were needed. Children played outside during periods of peak fallout and pregnant women worked in their gardens. Families ate their locally-grown produce, milk and meat contaminated with fallout radionuclides, with little early evidence of the insidious injuries which were being sustained. The AEC used Public Health Service and media professionals and consultant professors to convince a trusting public that there was no hazard, no need for even the simplest measures to protect themselves against nuclear fallout.

More people began to die of leukemia even in the early 1950's. High concentrations of radioiodine were found in the thyroids of children. These effects could not be reported because, according to a Deputy Director of the Atomic Energy Commission, "We can't change our story now; we'll be in trouble". A few scientists at the time who objected were told by the Chair of the Joint Committee on Atomic Energy "Listen, there have been a lot of guys like you who tried to interfere with the AEC program; we got them and we'll get you". Many instances of deception, disinformation, and intimidation of concerned scientists are now part of the public record.

With this background, where are the studies of population effects around nuclear facilities? The nuclear establishment, like chemical, asbestos and tobacco industries, has resisted objective, aggressive efforts to study the effects of its radioactive releases on human health. A striking example is an AEC internal memo from a high-ranking AEC officer to AEC Commissioner Haworth, Chairman Seaborg, and the other AEC Commissioners and the Federal Radiation Council Working Group (attached). In addressing the need for studies of health effects from radioactive fallout, instructions are given on how to conduct such research:

> "...start with a simple, straightforward statement of conclusions. We would then identify the major questions that could be expected to be asked in connection with these conclusions. It would then be a straightforward matter to select the key scientific consultants whose opinions should be sought in order to substantiate the validity of the conclusions or recommend appropriate modifications".

The "key scientific consultants" would include not only their own in-house scientists, but also professors from status-lending universities willing to serve as consultants or to support agency doctrine in

exchange for annual renewal of their research funds, or anticipated future benefits. These "key scientific consultants" are "the respected scientists from noted universities and research institutes", the so-called scientific peers who review manuscripts dealing with radiation effects.

Despite this Orwellian version of the scientific method, few studies have actually been done of the effects of radioactive fallout or of the effects of radiation on nuclear plant workers. Even fewer studies have been done of the health effects induced by radioactive exhaust plumes and contaminated water released from nuclear installations, i.e., the Savannah River Plant and Hanford, where some hundreds of thousands of curies of radioiodine were released in the 1940's.

The research on radiation effects which has been sponsored by the AEC and its current counterparts, the DOE, the Nuclear Regulatory Commission, and the Office of Radiation Programs of the EPA, has been self-serving to the nuclear industry. Some examples of this sort of research include:

- the consistent minimization of the actual toxicity of nuclear materials;
- AEC and DOE testimony in the Utah lawsuits denying that the deaths of thousands of sheep were caused by fallout from nuclear weapons tests;
- studies of cancer deaths, rather than cancer incidence in plutonium workers, comparing the highly selected nuclear workers to the general population;
- the standards of permissible body burdens of plutonium and similar transuranics for the public and for nuclear workers, which permit serious chromosome damage;
- the trivialization of exposure to uranium;
- the non-protective permissible limits for radioactive tritium in water.

Using the official (but non-protective) DOE guidelines limiting radioactive materials for nuclear workers, it can be calculated that one cubic centimeter (one-quarter teaspoon) of plutonium-239 represents the permissible body burden of plutonium for 45 million nuclear workers, or more than 4 billion people. Where are the surveys of plutonium and other transuranics in respirable dust around TMI? One cubic centimeter of plutonium-238 would exceed these limts for 11 billion nuclear workers or one trillion people. Polonium-210, used as an "initiator" for most nuclear weapons until at least 1957, is 56,000 times more radioactive than plutonium-239. We can contrast these tiny amounts...one-quarter teaspoon...with many tons of plutonium produced by the DOE in four

reactors that operate without containment at Hanford and at the Savannah River Plant. Our 90 commercial nuclear reactors produce an additional 5-10 tons of plutonium annually. These extremely toxic reactor wastes must be reprocessed to manufacture nuclear weapons.

Individual scientific research on health effects in this area has been discouraged because of lack of funding, and lack of basic information concerning actual releases of radionuclides from nuclear installations. As recently as 1978, Department of Energy spokesmen alleged that plutonium levels in air near the Rocky Flats plant were near that from background. In fact, another branch of the DOE, the Environmental Measurements Laboratory, had measured plutonium levels around Rocky Flats for a number of years as part of their 50-station Plutonium-in-Air Network. For every month measured the Rocky Flats area had the highest levels of plutonium in air reported in the world.

Where are the published reports of the research that the DOE has done over the past 40 years of effects on populations from fallout or from offsite contamination around nuclear plants, or of effects on workers? Are we to believe that there are no effects? The most recent citation in BEIR 80 was published in 1979. More than 17,000 scientific reports on cancer causation have been published since 1979, but have not been cited by the BEIR Committee.

The DOE denies that their health studies are conducted by federal employees, but they rely on "a network of national laboratories to conduct those studies", as if to say that they have laundered the money by passing it through a national laboratory so that these are no longer DOE funds. The professor at a university gets large sums of money to do research for an agency which is quite protective of its interests. The professor will take care not to jeopardize the annual renewing of his research funds. I cite as an example the case of Dr. Edward P. Rack, Professor at the University of Nebraska, whose research is supported by the DOE, and who is "an expert involving radioactivity". Professor Rack agreed to provide expert testimony in an action taken by a Rocky Flats worker claiming injury due to plutonium deposition in his body. I have attached depositions and a letter indicating how Professor Rack was intimidated by a threat of losing his DOE grants, causing him to withdraw as a consultant/expert witness from this case. The key scientist at the national laboratory is in a similar situation.

Further, a study conducted by other federal agencies in collaboration with the DOE must have a DOE sign-off before it can be released. The national laboratories not only do health studies, they also develop nuclear weapons and do related research. It is clear that the priority of the national laboratories is to serve the overriding mission of the DOE, which is not to protect the health of the worker and the public. I believe the record of the national laboratories in this area is very poor. These research funds should be diverted to new and independent research scientists who operate outside of the system.

The DOE invokes the mystique of nuclear technology for studies of cancer induced by radiation, citing the technical capability necessary to "analyze and understand the extremely complex data involved in these studies". This is a dodge that has been used over the past 40 years by the nuclear establishment with considerable success. In fact, such studies need not be difficult. For example, the EPA speaks of radionuclides in picocuries per gram of soil, picocuries per liter of water, and picocuries per cubic meter of air. In contrast, the DOE and NRC adhere to an odd and awkward physicist's pig-latin, discussing contamination in terms of "10^{-12} uCi per ml", i.e., ten to the power of minus twelve microcuries per milliliter. A man does not usually think of inhaling milliliters of air when he inhales 20 cubic meters of air in a day (20 million milliliters). The DOE and NRC personnel can scarcely manage their own awkward terminology, and I have seen their senior scientists become quite confused in dealing with these terms. I cite this as an example of the efforts to make radiation matters seem obscure and remote to the general public.

The DOE itself insists on funding badly designed studies and relies on studies of cancer deaths, a poor measure of effect on populations. The more sensitive and stronger cancer incidence studies have usually been neglected, and there are few such studies which have been published by DOE-supported researchers or by the DOE national laboratories, which have been feeding at the public trough far too long. On the other hand, research conducted by the Department of Health and Human Services has usually been more productive. Compare the ratio of DHHS-supported studies in BEIR-80 to those supported by DOE/NRC.

The DOE acknowledges the conflict between their principal and overriding responsibility to produce nuclear weapons and nuclear materials and their role as advocate of the health and welfare of their employees, but fails to note also their need to protect the DOE and its corporate contractors from suits by injured employees and the public. The DOE really has no good argument against the transfer of authority to conduct radiation effects studies to the DHHS. I am convinced that this administrative action would result in more effective use of public tax dollars and that, for less money, we would have radiation health studies of higher quality and reliability and certainly with much greater objectivity than those conducted by the Atomic Energy Commission, or, as it is known today, the Department of Energy.

III. The objections of DOE's sister agencies to S-525 are poorly supported.

The DOE cites the support of sister agencies who are unwilling to oppose the Administration position.

The United States Nuclear Regulatory Commission cites the comments of their General Counsel, Herzel H.E. Plaine, who endorsed the transfer of radiation epidemiology research programs from DOE to DHHS and so would support S-525.. His position reflected prior endorsement of the 1979

recommendations to the President by Joseph Califano, then Secretary of HEW. The NRC also cites NRC Commissioner Asselstine, "who believes that public health-oriented agencies, such as NIH, are best suited to have primary responsibility for radiation effects research, including epidemiology studies" and "Consequently, he would prefer the reorganization proposed in S-525 to the current situation".

However, other members of the Commission "see little benefit to be gained by transfer of ionizing radiation epidemiological research programs from DOE". These members of the Commission base their position in part on the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) created in 1984 under the Office of Science and Technology Policy in the Executive Office of the President.

Their objections are poorly supported. They think that the transfer of the human epidemiologic studies from DOE would separate this research from animal research on radiation injury mechanisms as if that would make a difference. Perhaps they would support the transfer of all such research to DHHS. They should have acknowledged their own conflict of interest position as a sister nuclear agency that also funds studies of radiation effects on health. The NRC is recognized as an agency that actively supports the interest of nuclear power, and cannot be represented to be objective concerning issues over the health effects of radiation, and neither are the NRC contractors.

They allege that the current DOE Epidemiology Program "seems to be adequately supported and technically well-managed", but this allegation is not supported. They cite review by their "scientific advisory panel" and report that results are "openly published in peer review journals". In fact, very little research has been published in the recognized scientific journals which has any relevance to the concerns about the effects of DOE activities on workers and the general public. They state that the DOE "may provide a more stable funding level than other agencies". It is certainly true that the DOE has spent a great deal of money over the years to very little effect for this sort of research, and that a change has been in order for some time.

The EPA opposes S-525 and this position, I believe, reflects the input from the Office of Radiation Programs, an office which in the past has been staffed by former members of the AEC. Thus, it is not surprising that they would show loyalty to the AEC and the nuclear industry from which some members will later seek employment. An example of their lack of objectivity is the specific exception of uranium from the EPA drinking water regulations of 1977, and their controversial guidelines for plutonium and other transuranics in soil of 1978, which were never signed into law by either President Carter or President Reagan.

The EPA position is also poorly supported. They say only that the transfer "could result in a less clear focus for the epidemiology program and a lack of coordination between the epidemiology program and

other radiation programs. This interesting statement can be interpreted in two ways, if you consider, as I do, that the current focus for the DOE epidemiology program is to protect the corporate contractors and the DOE from suit by injured workers and members of the public.

The Science Advisor to the President does not support S-525, but really provides no substantive support for his position. The Advisor does not question DHHS's credibility, "nor that agency's ability to do an excellent job" but he states "the radioepidemiological studies conducted by DOE are interwoven into and supported by the national laboratory system, with all its staff and contract programs". Again, this is an interesting sentence. As I interpret it, it means that we can be assured that these studies conducted by DOE will not provide any embarrassment to DOE and its corporate contractors, by finding any evidence of effects from radiation exposures to the worker and the public. This relationship was addressed by the AEC memo on fallout studies, I believe. I believe that research produced by this system has not been timely, and has been biased and of poor quality.

The Advisor depends on two National Academy of Science studies on the question of a transfer. Again, this is a needless waste of public funds, to belabor a decision which should have been purely administrative. Those studies found that DOE had need for an increased use of a formal peer review process, increased publication of study results, and increased interagency communication. It seems to me that these recommendations do not really address the question of why this transfer should not occur. While the Advisor states "there seems to be numerous salient arguments against passage" he does not cite a single argument in his letter of comment to Senator Roth.

Former Secretary Heckler of DHHS simply defers to the Science Advisor to the President. She denies evidence for claims of conflict of interest but provides no assurance that she has really looked for any. She suggests an outside scientific advisory body, presumably of "key scientific consultants", again seeking to avoid the simple administrative wisdom of assigning to a department the activities which are consistent with that department's mission. She closes with "we are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program".

It is my view that the DHHS should conduct its work independently of its sister agencies. In this way it can maintain its objectivity and its respect and acceptance by the public. In the past, DHEW apears to have been easily intimidated by other agencies and its reputation has suffered, and it has been used for personal advancement by individual members of its staff, who have traded on their position in my opinion. Where this agency funds research in collaboration with its sister agencies, such as DOE, both agencies must sign off before reports can be released, and this raises questions of conflict of interest. Further, I hope that there will be a strengthening of the federal ethics

regulations so that DHHS staff and DHHS-funded scientists can be expected to produce reports not compromised by the qualified funding of their work. If the research impacts on some industry or special interest group, the researcher should not receive funding or other considerations from such industries or special interest groups after producing work supporting the interests of an industry or a special interest group. Other agencies, such as the DOE, NRC or "the Administrative program," should not be permitted to apply pressure on the DHHS to compromise their work.

IV. Questions about the performance of the Department of Energy as an advocate for the worker and the public, and the DOE role as monitor and source of funds for studies of the health effects of radioactive materials.

Why should the Department of Energy oppose the transfer of radiation health studies to the Department of Health and Human Services? I offer some questions to DOE concerning their performance over the past 40 years.

1. I understand from Mr. Boggs of the DOE that the DOE (AEC) has supported epidemiological studies of the effects of radiation for about 40 years. I ask exactly how much money has been expended for this purpose by the DOE and its contractors and grantees over the past 40 years, in total? How many reports/other studies have been published in the important scientific journals in this country and what will the cost have been for each such report, that is, dividing the number of such reports by the hundreds of millions or billions of dollars which have been expended by the DOE/AEC for radiation studies over the past 40 years.

2. Over the past 40 years how much money has been given to the national laboratories? How much for each laboratory? Exactly how many reports of the effects of radiation have been published in the major scientific journals by the national institute scientists or their subcontractors? Dividing the number of these journal publications for the total budget over the past 40 years, what is the cost for each published report of significant research in widely recognized scientific journals for each of the national laboratories?

3. The DOE has a maximum permissible body burden for plutonium in nuclear plant workers of 40 nanocuries, or 40,000 picocuries, representing 88,000 nuclear disintegrations per minute of plutonium in a person's body. Each single nuclear disintegration of plutonium yields an alpha ray with greater than five million electron-volts of energy which may kill or seriously injure five cells. A study of chromosome injury among nuclear plant workers at Rocky Flats found that doses of only 1% to 10% of this maximum permissible DOE dose caused a 33% increase in the rate of

chromosome aberrations in circulating lymphocytes. Why does the DOE permit such a standard in the face of this evidence of permanent injury? The excretion rate of plutonium from body organs is very slow, about one-half in 200 years for bone, for example.

4. The DOE expresses concern for hazards to workers. However, I recall in the early 1970's at the Rocky Flats plant that a clerk was transferring files in her office from one file to another, and pulled out a file folder marked "P" from which a quantity of plutonium dust in a fragile container fell and burst on the floor, contaminating the area. I remind the Committee that, for example, one teaspoon of plutonium-239 would exceed the maximum permissible body burden (even using the nonprotective DOE standards) for 140 million nuclear workers or 14 billion people. If the plutonium had been plutonium-238, a teaspoon could exceed the DOE nonprotective body burden limits for 45 billion nuclear workers or 4 1/2 trillion people. My question is, does the DOE maintain a record of similar incidents at all of the other plants which they own or operate, and, if so, are these records available for inspection so that we can appraise DOE's record of safety and concern about hazardous exposures to workers and the public? Have such records gone to the shredders?

5. Plutonium, americium, curium and several hundred other radionuclides which are released by DOE facilities must be retained within the plant by use of hundreds of large industrial filters that filter the exhaust. The handling of these filters is important. Filters have been installed backwards at Rocky Flats, permitting quantities of plutonium to escape. On one occasion the filters were not changed for more than four years of plant operations, until an explosion blew out all 600 plus filters in the main stack. Based on plant studies of rates of accumulation of plutonium on filters, those filters could have contained as much as a quarter ton of plutonium. There was a fire which accompanied the explosion, and a black plume of smoke blew from this stack over the Denver area for about half a day. Is this incident consistent with an agency which maintains it is interested and concerned about radiation exposures? How many other such incidents have occurred involving industrial filters and stack releases, such as the release by Hanford of hundreds of thousands of curies of radioiodine in the 1940's?

6. After the 1957 explosion blowing out the filters, and the fire at Rocky Flats, the plant sent out a survey team to measure offsite contamination. They found very high levels of contamination with weapons-grade uranium at an elementary school twelve miles south and at a second elementary school playground area six miles east. They did not report plutonium levels at the schools, but did report very high levels of plutonium on private land in between the two schools. This information was never reported to the public or to

local public health authorities, but had to be obtained through discovery proceedings in a large lawsuit brought by landowners against the DOE and its corporate contracters, Dow Chemical and Rockwell International. How does this indicate DOE concern for the health of the public?

7. In a review of the records of a DOE worker at Rocky Flats I learned that he had been exposed "to a brilliant flare-up in a glove box" while working with plutonium ingots, which left him dazed and dizzy for several hours afterward. Exactly what is "a flare-up in a glove box" involving plutonium ingots? What would the radiation dose to the head have been? There was no radiation dose indicated in the worker exposure records from this incident. This man later died of a brain tumor which has since been found to be associated with his exposures to plutonium by hearing officers in Colorado.

8. We are now aware that there are serious hazards with operating nuclear reactors without containment vessels. Why then does the DOE continue to operate four such reactors without containment vessels at Savannah River Plant and at Hanford, Washington?

9. Why does the DOE persist in funding studies of cancer deaths when these are poor studies, i.e., half of persons contracting cancer die of some other condition and so are not counted in such studies. These studies are delayed for years or decades because of the survival period after contracting cancer, and the lengths of such studies allows more confounding to take place, i.e., persons being lost to the study or being included in the study without having had early exposures to radiation. Why doesn't the DOE do cohort studies of cancer incidence in workers stratified by levels of radiation exposure, by period of exposure and by number of years on the job, etc. considering such factors as smoking, education and religion (in case of Mormons and Seventh Day Adventists), etc.?

10. Why does the DOE have a concentration limit for uranium in the water of 6,000 picocuries per liter, when there is evidence, supported now by two EPA advisory letters, that concentrations of uranium be no greater than 10 picocuries per liter. The EPA guidance is based on estimates that higher doses will cause unacceptable health effects.

11. Why does the DOE have a limit for tritium in water of one million picocuries per liter, when the EPA permits no more than 20,000 picocuries per liter?

12. At the conclusion of a lawsuit by landowners against a DOE plant in Colorado at Rocky Flats, DOE, Dow and Rockwell paid the landowners a settlement of $9 million. The contaminated land will never be used for housing. It has been reserved for open space and industrial parks. Why did the DOE insist on reclaiming all of the

DOE documents confirming unacceptable levels of contamination and AEC/DOE incompetence and mishandling after the trial? Have these materials and similar materials in other DOE installations now gone to the shredder?

13. The DOE has operated over the past 40 years serving as a conduit for billions of dollars to the University of California and many other universities which in turn have subcontractors and consultants, etc. Is there a complete list of all the universities, colleges, medical schools, professors, laboratories, industrial concerns, corporations, individuals who have received this patronage? How many of the "key scientific consultants" on the patronage lists serve as peers to review manuscripts on radiation effects and journals in this country?

14. Has the DOE/AEC supported research involving radiation exposures to human subjects? I refer here to research by Dr. Saenger and Dr. Lushbough. Are there others who have been involved in doing such research involving radiation exposure to human populations? (Including here the injection of large amounts of plutonium into a number of persons in an experiment supported by the AEC).

15. How many former AEC/DOE personnel now work for the nuclear industry? How many now work for the Office of Radiation Programs for the EPA or the NRC? How many are now university professors, still used by the DOE as "key scientific consultants"? How many are directors of institutes, or consultant firms, supported by contract work for the AEC?

16. How does the AEC/DOE explain their behavior during the period of atmospheric bomb testing, which in my opinion, was criminal? How does this square with their view that the DOE must be the agency to determine if radiation has injured workers or the public?

17. DOE has had a slush fund which was used for various undisclosed purposes. How many funds have been spent by the DOE through the so-called slush fund or similar funds over the past 40 years and for what purpose? Are these used for political contributions? Are these used for undercover activities or what?

18. How much money has the DOE spent on public relations, for media consultants and PR firms over the past 40 years?

19. How many AEC personnel or those supported by AEC/DOE funds now have high ranking positions in corporations, working with large nuclear interests? How many serve on boards of directors?

20. With the DOE concern for the health of the public, what have we learned from the AEC/DOE over the past years about the true nature of the hazard of the thousands of tons of high level nuclear wastes

stored on-site at reactors and at weapons production facilities? A single nuclear reactor core like one at Three Mile Island contains about one hundred tons, or 100,000 kilograms of fissionable material; uranium and transuranics, like plutonium, curium, americium; forty-seven isotopes of importance all together. The Hiroshima bomb, on the other hand, contained only 12 1/2 kilograms of uranium so that a single nuclear reactor core contains the same amount of fissionable material as about 8,000 Hiroshima bombs. About one-third of the core must be replenished every year, equivalent to about 2,700 Hiroshima bombs. We have today 101 nuclear reactors operating in this country which produce high level radioactive waste equivalent to about 300,000 Hiroshima bombs each year. What is the total amount produced by the weapons industry and the nuclear power industry to date in the United States that must be stored in perpetuity? How much for the whole world? The half-lives of these materials range into the millions of years. Plutonium 244, for example, has a half life of 82 million years. Curium, which is a heavier sister of plutonium and equally toxic is produced in even greater amounts on a curie basis than is plutonium. There are very large amounts of these heavier transuranics. Can we trust the DOE/AEC to protect us in perpetuity from these ultra-hazardous substances, considering their extreme toxicity?

V. Summary

Under the leadership of the Atomic Energy Commission and the Department of Energy, research has not proceeded satisfactorily into the health effects of radiation exposure from such sources as nuclear bomb tests; the manufacture of nuclear weapons; risks of residing near nuclear production facilities, nuclear power plants and radioactive wastes; and the medical uses of nuclear materials.

An important purpose of basic research and epidemiological investigations of the effects of radiation and the hazards of environmental contamination is to provide a foundation for meaningful and protective public health rules and regulations and concentration limits, which must then be enforced. The effect of involving DOE in this underlying research is to place the fox in charge of the chicken house or to hire a Willie Sutton to guard the bank (Willie Sutton was a notorious bank robber). If the DOE should sponsor research with results that would do injury to its mission, there will be an obvious motive for suppressing such information, or more likely, to avoid funding such research in the first place, or to choose "key scientific consultants" who can be relied upon not to produce damaging evidence.

We do not expect much meaningful research on the health risks of smoking or of the use of snuff to come out of research activities of "key scientific consultants" funded by the tobacco industry or its scientific institute. We do not expect to see important research concerning the

hazards of exposure to asbestos published by "key scientific consultants" funded or hired as senior scientists or vice-presidents by Johns-Manville Asbestos Company and the "key scientific consultants" of the American chemical industry are not widely known as authors of research studies pointing up the hazards of exposure to PCB's, dioxin, pesticides and other compounds hazardous to chemical plant workers and the public.

Similarly, the DOE, which owns many large industrial installations and has contractual relationships with many large corporations like Dow Chemical Company, Rockwell International and Union Carbide, has been generally ineffective in this task of conducting the basic research, the animal studies and the epidemiological investigations into the effects of exposure to the products and the wastes of the nuclear industry.

I think tax money has been squandered by relying on a nuclear weapons production agency to do health research. At a time when we are called on to economize in public expenditures, it makes good business sense to use these health research funds more effectively by granting these funds to the agency whose business or primary mission is the protection of public health and the health of the worker. This is simply a matter of good administration practice, as I reported to the Interagency Task Force on the Health Effects of Ionizing Radiation at their Denver meeting in 1979.

I urge that this legislation be supported. I thank the Subcommittee for allowing me to present this testimony. I sent earlier a number of exhibits to support my testimony, and I would be glad to discuss each exhibit.

Since an advance copy of my testimony had to be submitted to the Chairman by May 5, 1986, and had to be prepared with short notice, the manuscript that I offer into the record today is an improved draft of the preliminary manuscript.

Sincerely yours,

Carl J. Johnson, M.D., M.P.H.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

CIVIL CASE NO. 85-F-1347

NEAL B. DARR, Plaintiff,

vs.

ROCKWELL INTERNATIONAL, Defendant.

AFFIDAVIT OF KENNETH COBB

STATE OF NEBRASKA)
) ss.
COUNTY OF LANCASTER)

Kenneth Cobb, being first duly sworn on oath, sayeth as follows:

1. That he is one of the attorneys for the plaintiff, Neal B. Darr.

2. The he was present during the taking of the deposition of Dr. Edward P. Pack at 1701 South 17 Street, Lincoln, Nebraska, being affiant's office, on the 11th day of March, 1986.

3. That upon the completion of the oral testimony of Dr. Edward P. Rack at approximately 12:27 p.m. on the 11th day of March, 1986, a seemingly innocent conversation took place between Jake J. Chavez and Dr. Edward P. Rack, to wit:

a. Jake J. Chavez did say to Dr. Edward Rack, to wit, "Oh, you may be getting a call from Dr. Bob Marianelli."

b. Dr. Edward P. Rack replied that he knew Bob Marianelli, having known and worked with him for approximately 18 years; Dr. Rack then inquired if Jake Chavez knew Dr. Marianelli.

EXHIBIT A

c. Jake J. Chavez responded he did not know Dr. Bob Marianelli, but had gotten the name from the Vita of Dr. Rack, and that Dr. Rack would be getting a call from Dr. Marianelli.

d. Immediately thereafter, Dr. Rack became agitated, nervous and requested to see the affiant in person in affiant's office, which was done.

e. Dr. Rack then advised the affiant he could no longer be involved as an expert witness in the case because he was being "intimidated". Dr. Rack advised that he receives research grants from the U.S. Department of Energy for his graduate student chemistry program at the University of Nebraska, Lincoln. Dr. Bob Marianelli is Acting Chief of Chemical Sciences, U.S. Department of Energy, Washington, D.C., and in fact receives all research proposals from Dr. Rack and the Department of Chemistry, University of Nebraska, Lincoln. Dr. Marianelli is very instrumental in approving grants and funding for those proposals. It is impossible for the graduate program at the University of Nebraska, Lincoln, to continue without that government funding. Dr. Rack repeatedly affirmed that he definitely felt threatened.

4. The curriculum vita of Dr. Rack shows at page 2 the amounts and sources of funding granted to Dr. Rack's program. Further, said vita does not contain the name of Dr. Marianelli. Affiant furnished a copy of the vita to defendant's counsel by personal service on February 14, 1986 and also by mail on the same day. Attached hereto and made a part hereof as Exhibit 1 is a copy of said Vita.

5. Dr. Rack has since informed affiant that he is more convinced than ever that he has been threatened, and his existence and his continuance as a research chemist is threatened.

6. That the affiant has talked with Dr. Rack on more than one occasion since March 11, 1986, and the latter has expressed a very sincere fear and concern for the future funding of his graduate student program.

Further affiant sayeth not.

Kenneth Cobb

SUBSCRIBED AND SWORN to before me, a Notary Public, this 18 day of March, 1986.

RONDA JACKSON
GENERAL NOTARIAL
STATE OF NEBRASKA
COMM. EXPIRES
SEPTEMBER 20, 1989

Ronda Jackson
Notary Public

KENNETH COBB
Attorney at Law

LAW OFFICES OF
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BEST AVAILABLE COPY

MEMO

TO: KEN AND DARR FILE 493-1

FROM: DR. RACK (TELEPHONE CONVERSATION)

DATE: MARCH 11, 1986

Dr. Rack called at approximately 2:45 on March 11, 1986 and this is were Renna taped the conversation Dr. Rack was having with Mr. Cobb.

R: But where does that leave us in terms of a case - they are going to question me in plutonium. You heard what Jake baby said. Do you know anything about plutonium first hand? That is a question. The point of the matter is, we have evidence or you have evidence on this matter which has to be with the Transuranium Registry. Anybody who is a registered health physicist, anybody, can read that type of documentation. This is the point, anybody who wants to do this. There are consulting firms that are national that can do this kind of stuff. I am very worried frankly, Ken, of getting involved with this hard ballgame, to be honest with you.

C: Will you do this for me though?

R: Yes?

C: Will you back me up as to what they did?

R: I, uh, well, the statement that you said, yeah, I'll back you up on that but, I mean, I, my back is against the wall.

C: I know.

R: I mean, I have made calls, you know, New York, Omaha, Washington and while everyone says no, but I mean the handwriting is on the wall. I am reading between the lines what these people are saying to me. You understand that Ken?

C: Yeah.

R: You understand?

C: Oh, I understand 100% and that is exactly what they are trying to do.

R: Uh, huh, that's right, they're exactly what they are trying to do. But I can assure you that with your testimony that you have basically in the literature, the Rocky Mountain Flats, all that stuff, you have got an excellent case. It's just somebody who doesn't have any DOE ties to read it in court that it can say yes, I am a registered health physicist. I am a member of the Health Physics Society. I have dealt with monitoring these things. I know how to do these things. This is my journal. I subscribe to it. I am quite familiar with it. This is what you need, you need people who tell, who can state this, are people who have done research. But then they have got you behind the ballgame there. Everyone who does research in plutonium is supported by the Department of Energy. You read me don't you?

C: Oh yeah, 100%.

R: Ok, so like, so they have this fan club here and I felt not only intimidated but really smashed, you know, to a pulp. I mean, oh yes, this is a free country, sure. You can say whatever you want to but just don't make a fool of yourself is basically the word I was saying or keep a high profile. And basically what that means is that the case gets blown up in stature, which it probably will and I am sure it will, you see. I mean here I am a DOE contractor, they're getting this publicity and I will get screwed. And I can promise you one thing, if I do go to court it is professional suicide and this is where I stand right now, Ken.

C: I will not force you to go to court. The only thing I am asking you to do is will you back me up on what is said?

R: I will back you up with what was said. I will, because Chavez is a lawyer and he is in no way associated with me personally. I will back you up with the statement that he made. Period,. I will back you up.

C: Well and that you are afraid for your future. Because of this.

R: I am uncertain about my future. I will, I can say that. Yeah, I'll say that, now who, what do you want to do with this Ken is what I am trying to figure out

C: What I am going to do is move to disqualify him as a lawyer.

R: I will back you up on that.

C: And that he should be reprimanded or subject to disciplinary procedures in the Bar Association.

R: I will back you up on that.

C: And that when he made this comment, this is what it meant to you.

R: It meant very much to me. It meant that in fact Marianelli in Washington said that, uh, yeah he talked to me but he only questioned about who I was. In other words, asking about my expertise and what he found out that I was a somebody in the world. I mean, it's all the things that they are finding out, you know this. I will back you up on that statement regarding Chavez. I will back you up on it.

C: I am going to have a little fun with this man. I --

R: I am very upset, Ken. I really am.

C: I know you are and I want to convince you and show you that this is NOT the kind of thing that goes on in this world in the judicial system and we are not going to stand for it and we are not going to let them get away with it.

R: As long as this doesn't have to do with the DOE per se - it's only an attack on him as personally.

C: It will be strictly an attack on him.

R: Personally?

C: Right.

R: Ok, as long as it is on that. But I understand and I can read and I am sure you understand what I am saying.

C: I know 100%.

R: Uh,huh.

C: And I have no doubt and there is no way in the world I want in any way, you to lose grants, lose your prestige or have anything happen.

R: But you know that would happen. It would happen. I mean, the word gets around, I know the way the system works, that somehow I would get the most difficult reviewers who would give a very honest opinion and say that what I do is bullshit and they would believe it. The point is the system is manipulated and it can be manipulated legally. You understand that?

C: I know what you are talking about.

R: Uh, huh. Right. Just that suggestive reviewers get these guys who really screw everybody because they hate the world. So I get them and they tell me I am a real turd and that's the whole point in the system. There is no way you can fight against this and I know and I have dealt with it because I have been part of the process and review, peer reviews for grants and whatever. So I know how it works. Oh, boy, but this guy has to go. This guy is a son-of-a-bitch.

C: I agree and I want to get him.

R: So go get him.

C: Alright. I am going to need your help.

R: Ok.

C: Alright and, uh, I'll get back to you but as far as, unless something drastically changes, I will not consider you, using you as an expert witness.

R: That is correct. Now do you want then for me then offically to be terminated then as your consultant?

C: No. Not yet.

R: Ok.

C: But I will, uh —

R: Have you been keeping a tab on my hours? I mean, if you want to do that or whatever or how you want me to work that?

C: I've got a pretty good tab on it.

R: Ok, so you run the tab and whatever you think I was worth. Ok, KEn?

C: Alright.

R: Ok, but, you know, now you have got the documentations so you are willing to use, I mean, you are welcome to use it.

C: ALright. I'll get back to you.

R: Ok, Ken.

C: Thank you.

R: Bye, bye.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

CIVIL CASE NO. 85-F- 1347

NEAL B. DARR, Plaintiff,

vs.

ROCKWELL INTERNATIONAL, Defendant.

AFFIDAVIT OF RENNA RITCHIE

STATE OF NEBRASKA)
) ss.
COUNTY OF LANCASTER)

Renna G. Ritchie, being first duly sworn on oath, states as follows:

1. That she is a Legal Assistant, employed by Law Offices of Cobb & Hallinan, P.C. at 1701 South 17th Street, Lincoln, Nebraska, and has worked with Kenneth Cobb, one of plaintiff's attorneys, for more than 15 years.

2. Affiant was present during the latter part of and after the deposition of Dr. Edward P. Rack taken on March 11, 1986 at 1701 South 17th Street, Lincoln, Nebraska. In addition to the witness Edward P. Rack, and Beverly Morgan, the court reporter, also present were Kenneth Cobb, Jake J. Chavez, Michelle A. Reynolds and Richard G. Cuddihy.

3. After the depcsition of Dr. Rack had been concluded, affiant was present during a conversation between Jake Chavez and Dr. Edward Rack, as follows:

(a) Jake Chavez commented to Dr. Rack that a Dr. Bob Marianelli probably would be calling Dr. Rack.

(b) Dr. Rack responded that he knew Bob Marianelli and had known him for at least 18 years as Dr. Marianelli used to be at the University of Nebraska. Dr. Rack added that Dr. Marianelli was now his monitor.

Cobb: Right.

Rack: Ok, as long as it is on that. But I understand and I can read and I am sure you understand what I am saying.

Further affiant sayeth not.

Reana G. Ritchie

Reana G. Ritchie

SUBSCRIBED AND SWORN to before me this 25th day of March, 1986.

GENERAL NOTARY-State of Nebraska
JOLEEN R. ROGGE
My Comm. Exp. Febr. 22, 1989

Joleen R. Rogge

Notary Public

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

CIVIL CASE NO. 85-F-1347

NEAL B. DARR, Plaintiff,

vs.

ROCKWELL INTERNATIONAL, Defendant.

AFFIDAVIT OF GORDON EHRLICH

STATE OF NEBRASKA)
) ss.
COUNTY OF LANCASTER)

Gordon D. Ehrlich, being first duly sworn on oath, states as follows:

1. That he is a junior at the University of Nebraska/Lincoln Law School, employed as a law clerk by the law offices of Cobb & Hallinan, P.C. at 1701 South 17th Street, Lincoln, Nebraska, and has worked with Kenneth Cobb, one of plaintiff's attorneys, for five months.

2. Affiant was present at the aforementioned Law Offices of Cobb & Hallinan on the morning of Saturday, March 8, 1986. On the same morning, before Kenneth Cobb had arrived, Dr. Rack arrived at the law office.

3. Affiant greeted Dr. Rack upon his entering the office and asked him if he would like a cup of coffee. Dr. Rack replied that he would and, therefore, I got him a cup of coffee.

4. Dr. Rack then stated to me "This is a very interesting case" that he "enjoyed reading" the material we had given him on the case.

5. Thereafter, I showed him what had been done by the DOE in a previous case as pertaining to expert witnesses and showed him the Findings of Fact, Conclusions of Law, and Order in the Gabel v. Dow Chemical &

(c) Dr. Rack then inquired whether or not Jake Chavez knew Dr. Marianelli.

(d) Jake Chavez replied that he did not know Dr. Marianelli, but that he had obtained Dr. Marianelli's name from the vita of Dr. Rack. Jake Chavez then advised he had called Dr. Marianelli previously to discuss the pending deposition of Dr. Rack. Mr. Chavez again stated that Dr. Marianelli would be calling Dr. Rack about the deposition.

4. Attached hereto and made a part hereof is Exhibit 1, the curriculum vita of Dr. Edward P. Rack. The name of Dr. Marianelli does not appear on said document.

5. After the departure of Jake Chavez, Dr. Edward Rack very tersely requested a private conference with Kenneth Cobb.

6. At approximately 2:45 p.m. the afternoon of March 11, 1986, Mr. Cobb received a telephone call from Dr. Edward P. Rack, at which time affiant was present in Mr. Cobb's office. The conversation of both parties was audible by a means of a speaker attachment. Upon my own initiative, a portion of the telephone conversation was recorded, which included the following:

Rack: Ok, so like, so they have this fan club here and I felt not only intimidated but really smashed, you know, to a pulp. I mean, oh yes, this is a free country, sure. You can say whatever you want to but just don't make a fool of yourself is basically the word I was saying or keep a high profile. And basically what that means is that the case gets blown up in stature, which it probably will, and I am sure it will, you see. I mean here I am a DOE contractor, they're getting this publicity and I will get screwed. And I can promise you one thing, if I do go to court it is professional suicide and this is where I stand right now, Ken.

Cobb: I will not force you to go to court. The only thing I am asking you to do is will you back me up on what was said?

Rack: I will back you up with what was said. I will, because Chavez is a lawyer and he is in no way associated with me personally. I will back you up with the statement that he made. Period. I will back you up.

Cobb: Well, and that you are afraid for your future. Because of this.

Rack: I am uncertain about my future. I will, I can say that. Yeah, I'll say that, now who, what do you want to do with this, Ken, is what I am trying to figure out.

Cobb: What I am going to do is move to disqualify him as a lawyer.

Rack: I will back you up on that.

Cobb: And that he should be reprimanded or subject to disciplinary procedures in the Bar Association.

Rack: I will back you up on that.

Cobb: And that when he made this comment, this is what it meant to you.

Rack: It meant very much to me. It meant that in fact Marianelli in Washington said that, uh, yeah, he talked to me but he only questioned about who I was. In other words, asking about my expertise and what he found out that I was a somebody in the world. I mean, it's all the things that they are finding out, you know this. I will back you up on that statement regarding Chavez. I will back you up on it.

Cobb: I am going to have a little fun with this man. I--

Rack: I am very upset, Ken. I really am.

Cobb: I know you are and I want to convince you and show you that this is not the kind of thing that goes on in this world in the judicial system and we are not going to stand for it and we are not going to let him get away with it.

Rack: As long as this doesn't have to do with the DOE per se, it's only an attack on him personally.

Cobb: It will be strictly an attack on him.

Rack: Personally?

Rockwell Int. Corp. case. Specifically, in this Order at page 7 was a typed paragraph that had been lined out concerning the tactics of the respondent's counsel Jake J. Chavez. After Dr. Rack had read this paragraph I stated to him that this is what he had to look forward to in this case because we were attacking the "establishment".

6. Dr. Rack responded by saying "You must remember I get grants".

7. I then showed Dr. Rack an article entitled "Widow Will Fight for Flats Death Pay", which stated that a Rocky Flats' employee had been contaminated at Rocky Flats and his brain, which was sent for an autopsy, was lost by the DOE. Then Dr. Rack read the article entitled "Widow Will Fight for Flats Death Pay".

8. Affiant had nothing further to do with Dr. Rack.

Further affiant sayeth not.

Gordon D. Ehrlich

SUBSCRIBED AND SWORN to before me this 22nd day of April, 1986.

RONDA JACKSON
GENERAL NOTARIAL
SEAL
STATE OF NEBRASKA
COMMISSION EXPIRES
SEPTEMBER 20, 1989

Ronda Jackson
Notary Public

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLORADO

CIVIL ACTION NO.85-F-1357

NEAL B. DARR, Plaintiff,

v.

ROCKWELL INTERNATIONAL CORPORATION, Defendant

AFFIDAVIT OF ROBERT S. MARIANELLI, PH.D.

Robert S. Marianelli, after being duly sworn says as follows:

1. I am Robert S. Marianelli, Ph.D., Acting Director, Division of Chemical Sciences, Office of Basic Energy Sciences, United States Department of Energy, Washington, D.C.

2. I am currently responsible for monitoring research conducted under certain grants made by the United States Department of Energy (DOE) to various academic institutions, including a grant to the University of Nebraska, Lincoln, for basic research in radiation chemistry under the direction of Professor Edward P. Rack of the Department of Chemistry.

3. Sometime during the week commencing on March 2, 1986, and before March 11, 1986, I received two telephone calls from Mr. Jake Chavez, an attorney with the

Albuquerque Operations Office of the DOE. In the first call, Mr. Chavez informed me that he was planning to take the deposition of Dr. Rack in a case concerning Rockwell International Corporation, a DOE contractor (the Darr case). Mr. Chavez then asked me to provide him with background information on Dr. Rack, including Dr. Rack's reputation in radiation chemistry, and whether Dr. Rack has a background in the biological effects of ionizing radiation, and specifically the effects of internally deposited transuranium elements.

4. In response to Mr. Chavez' question, I informed him that Dr. Rack was a well-respected radiation chemist whom I have personally known since 1966 when I was a faculty member of the Department of Chemistry at the University of Nebraska, Lincoln. I told Mr. Chavez that as far as I know Dr. Rack had not done research on the biological effects of ionizing radiation or on transuranium elements, but since I was ot familiar with Dr. Rack's entire career to the present, I eally was in no position to respond to such questions with authority.

5. On March 7, 1986, I received a second telephone call from Mr. Chavez. He asked me to provide him with some information on radiation chemistry which he felt would be useful in taking Dr. Rack's deposition. Mr. Chavez and I discussed the nature of the research done by Dr. Rack under his DOE grant.

6. In my conversations with Mr. Chavez prior to March 11, 1986, there was a clear understanding between us that Dr. Rack's participation as an expert for the Plaintiff in this case was a matter entirely separate from his research under the DOE grant, and there was no reason to believe that there should be any adverse impact on Dr. Rack's grant as a result of participation as an expert for Plaintiff. I indicated to Mr. Chavez that I thought I would call Dr. Rack and ask him about his testemony. Mr. Chavez suggested that I not call Dr. Rack until after the deposition on March 11, 1986.

7. On March 11 or 12, 1986, I received a telephone call from Dr. Rack, who expressed concern that his participation in the Darr case would have an impact on his research grant. I assured Dr. Rack that his participation in the Darr case was entirely up to him and that it was a separate matter from his research and that it would have no impact on his DOE grant.

8. A few days after my conversation with Dr. Rack, I received from him a letter dated March 13, 1986, which is attached hereto as Exhibit A.

9. On March 21, 1986, I received a telephone call from Mr. Chavez in which he requested that I provide this affidavit.

10. To my knowledge, no one within the Office of Basic Energy Sciences of the DOE has ever said to Dr. Rack that he should not or could not testify or participate in the Darr case.

FURTHER AFFIANT SAYETH NOT.

Robert S. Marianelli, Ph.D.

MARYLAND)
State of)
) ss:
Montgomery)
County of

Sworn to and subscribed before me, a Notary Public in and for Ocean City aforesaid, this 31 day of March, 1986, by Robert S. Marianelli, Ph.D.

Notary Public
Address: 1910 Rhodes Way
Gaithersburg, MD 20879
7/87

NOTARY PUBLIC

Please return

OFFICIAL USE ONLY

AN INTERNAL MEMORANDUM OF THE ATOMIC ENERGY COMMISSION (NOW THE D.O.E., N.R.C. AND THE E.P.A. Office of Radiation Programs)

SEPT 25, 1962

MEMORANDUM FOR CHAIRMAN SEABORG

THROUGH DIRECTOR OF REGULATION

SUBJECT: STATUS REPORT ON CURRENT ACTIVITIES OF THE FEDERAL RADIATION COUNCIL WORKING GROUP

The purpose of this status report is to call to your attention the activities of the Working Group with which I feel you should be acquainted.

Members of the Council were informed by memorandum, on September 20, that the Secretariat of the Council would have to vacate its quarters in the Executive Office Building, by October 1, and move to new quarters at 718 Jackson Place. I inspected the proposed new quarters, along with the other members of the Working Group. It is our unanimous conclusion that these particular quarters are totally inadequate to serve as a base for the Federal Radiation Council, particularly in view of the proposal to develop a permanent professional staff. I, personally, am of the opinion that new quarters should be sought as soon as possible. You may wish to include this problem, along with those of organization and qualifications of personnel, in the Subcommittee that is developing this subject.

The Working Group decided that the only efficient manner in which to proceed on plans for the preparation of the report on the health implications of fallout in relation to radiation protection standards and the applicability of countermeasures, would be to assign a specific member of the Working Group to act as the Project Leader. I was asked to accept this assignment and agreed to do so, subject to the concurrence of Dr. Western, Mr. E. Price and you.

Commissioner Ramey - 2 -

The Working Group spent one meeting considering alternative kinds of organization, format and content for the proposed report. I then undertook to write a project outline, submitting alternative ways to approach the report, both in terms of content and in the organization and execution of the study. The draft was reviewed at the last meeting of the Working Group, where it was concluded that the project really had to be divided into two phases.

1. It was agreed that current levels of radiation from fallout were too low to impose a practical problem in public health. It was suggested that the Public Health Service come up with its views as to what levels would correspond to enough of a health risk to justify diversion of resources in order to provide protection. If any reasonable agreement on this subject can be reached among the agencies, the basis approach in the report would be to start with a simple, straightforward statement of conclusions. We would then identify the major situations that could be expected to be said in connection with these conclusions. It would then be a straightforward matter to select the key scientific considerations whose existence should be assumed in order to substantiate the validity of the conclusions or recommend appropriate modifications.

2. Most two would recommend that all of the radiation protection philosophies which have been developed have dealt primarily with problems inherent in the control of sources, where it is recognized that lack of proper care can readily lead to demonstrable physical injury. It will be suggested by the Working Group, that the Council consider setting up a high level study group to examine this subject and present an advisory report to the Council.

Up until the present time, there has been no serious examination of what general national philosophy regarding radiation exposure matters would be most appropriate, as a basis of policy for the Federal Government. This is a rather deep subject that would require a highly sophisticated examination and could justify about a two-year study by a highly competent group. Depending on the depth and detail in which the questions were to be considered, this study could range anywhere from three months to two years. The three-month study would deal only with broad approaches and criteria, that could probably go no further. The longer study would be expected to be something almost as comprehensive as the recently published report by the United Nations, but with an orientation completely different than either the United Nations report or the corresponding

Commissioner Ramey - 3 -

study in this country, undertaken by the Biological Effects of Atomic Radiation Committee of the National Academy of Sciences. The problem in this case would be to investigate the influence of radiation quantitatively as a causative agent at all levels and rates of exposure in relation to other agents. The fundamental philosophy to which this study would be directed is that radiation protection measures against a course over which one has no control cannot be influenced by a "benefit-risk" concept or a concept such as "no radiation should be accepted unless there is good reason for doing so." Under these conditions, the relevant concepts would be that protection measures become justified when the risk of injury from radiation can be expected to start having a practical influence on a person's future life expectancy. Where or how genetic considerations should enter such concepts is not at all clear. Similarly, the philosophy of an appropriate cutoff point based on direct somatic effects, under non-emergency conditions, is also obscure. Better information relevant to these judgments made to be systematically developed.

I am proposing to concentrate on the first approach exhaustively until this possibility is either dropped, or is far enough along to justify consideration of the second. Any thoughts which you may have, which would be of assistance to me in this project, would be greatly appreciated.

Paul C. Tompkins, Deputy Director
Division of Radiation Protection Standards

cc: Chairman Seaborg
Commissioner Palfrey
Commissioner Ramey
Commissioner Wilson
Federal Radiation Council Working Group
A. R. Luedecke, General Manager
D. A. Ink, Assistant General Manager
V. B. McCool, Secretary (2)
C. L. Dunham, Director, Biology & Medicine
S. H. Woodruff, Director, Operational Safety

University of Nebraska Lincoln

Department of Chemistry
Hamilton Hall
Lincoln, NE 68588-0304
402-472-3501

file

March 13, 1986

Dr. Robert S. Marianelli, Chief
Fundamental Interactions Branch
Division of Chemical Sciences
Office of Basic Energy Sciences
Department of Energy
ER-141, MSJ-309, GTN
Washington, D.C. 20545

Dear Bob:

Since Jake Chavez of the Office of the Chief Council, USDOE, Alberquerque, contacted you regarding my possible role involving a civil case by Neal B. Darr, Plantiff v. Rockwell International Corporation, Defendant, I should inform you that I have withdrawn from the case as a consultant and/or expert witness for the Darr attorney, Mr. Kenneth Cobb of Lincoln, NE. It was my initial impression that the USDOE was not involved when the Darr attorney approached me about the case. However, it became quite obvious that USDOE interests were involved when USDOE counsels took my deposition on March 11th regarding my qualifications as an expert.

In no way would I want to embarass the Department and myself by my presence. While I may be an expert involving radioactivity, I certainly am not an expert in transuranic elements and health physics. I also feel that since this is out of my sphere of expertise, I should not fill my already overloaded schedule with non-essential work. Therefore, I notified Mr. Cobb, the Darr attorney that I have withdrawn completely as his consultant/expert witness.

Initially I was asked to comment on the accuracy of deposition statements made by Rockwell International Health Physicists and to discuss terminology with the lawyer. My conclusions to Mr. Cobb were that, based on the information in the deposition, the Rockwell International Health Physicists were quite competent, the company had an effective health physics program and that he could believe their assay results. I was also asked to comment on the toxic nature of various transuranic elements, which of course is quite well documented.

With best regards,

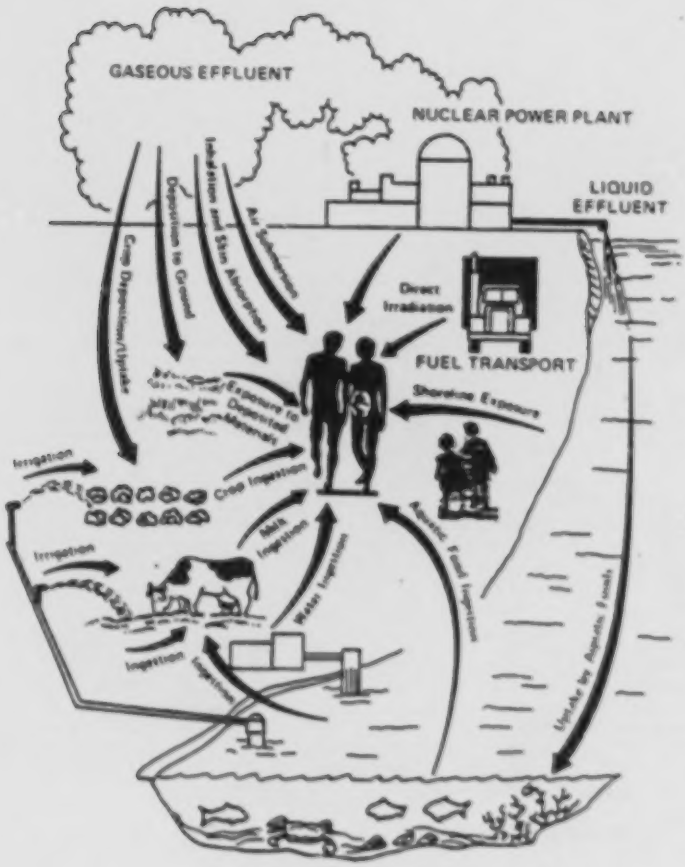
Sincerely,

E.P. Rack
Professor

EPR/jl

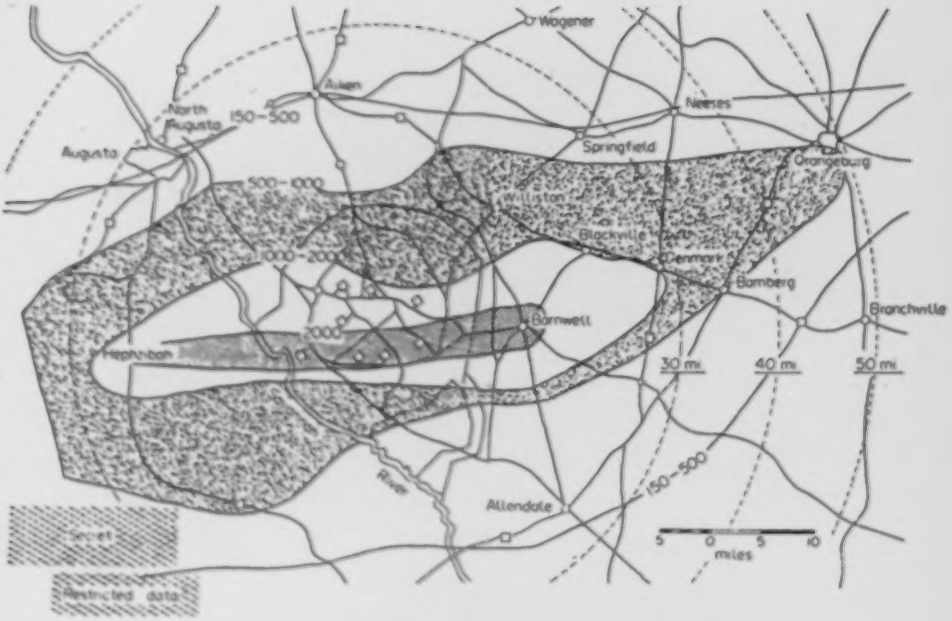
Figure 3 79.

Pathways of Radiation to Man



*This schematic figure is from NRC (Nureg-0139) and EPA documents. However, the children and the fetus have been added, since the NRC and the EPA consider only non-smoking adults. The children are about ten times more sensitive to radiation than the adults and the fetus about 20 times more sensitive. The children were taken from a photograph by W. Eugene Smith. (CJJ)

Figure 14



Concentric isopleths of radioactivity in cpm surrounding the Savannah River Nuclear Plant. Health Physics Regional Monitoring Semi-Annual Report, July-Dec., 1956. Works Technical Dept., E.I. DuPont de Nemours and Co, Explosives Department, Atomic Energy Division, Savannah River Plant, Aiken, S. Carolina. See p.5: Intensive Fallout on 14 March, 1955 -- "It appeared that the material was fallout from the Nevada atomic test."

Testimony of the

International Chemical Workers Union, AFL-CIO

Frank D. Martino, President

on

Senate Bill 525

Radiation Reorganization Act of 1985

June 17, 1986

Presented by
Thurman B. Wenzl
Industrial Hygienist

International Chemical Workers Union
1655 West Market Street
Akron, Ohio 44313
(216) 867-2444

My name is Thurman Wenzl; I am an Industrial Hygienist at the Health and Safety Department of the International Chemical Workers Union in Akron, Ohio. I would first like to thank the Subcommittee on Energy, Nuclear Proliferation and Government Processes for giving us the opportunity to express our support for Senate Bill 525 (the Glenn bill) transferring responsibility for radiation epidemiology studies to the Department of Health and Human Services. Our support for this bill is based on our experience which has shown that the Department of Energy is either unwilling or unable to order its priorities in a way which protects the health of workers and communities close to its facilities.

The ICWU represents workers at DoE facilities in Ohio and Tennessee; these include the Feed Materials Production Center near Cincinnati and the X-10 and Y-12 plants in Oak Ridge, Tennessee. At each of these plants, the ICWU is part of a multi-union Atomic Trades and Labor Council, which bargains directly with the DoE contractor about wages and working conditions - including health and safety matters.

The ICWU has one of the largest health and safety departments in the labor movement; I am one of 4 industrial hygienists on the staff, and we also have 3 health educators. Our responsibilities include advising the 50,000 members around the country on potential health hazards at work and what to do to minimize the risks. In addition to conducting formal classes on health hazard evaluation, we conduct walkthrough tours, make recommendations and investigate serious accidents.

During the past 2 years my responsibilities have included accident investigation and the evaluation of exposures to hazardous substances at the Feed Materials Production Center in Fernald, Ohio - near Cincinnati. This DoE facility had been operated by a subsidiary of National Lead until last fall, and is now being run by a Westinghouse subsidiary. It is primarily engaged in the production of uranium metal for reactors. I have visited the production areas of this plant 3 times during this period, and following each visit I have requested detailed information on airborne hazards and control strategies. There is worker concern at this plant about radioactive and non-radioactive hazards; these include, for example, acid mists as well as airborne uranium. In each case I have received only partial responses to my information requests, either because the exposure data I am seeking does not exist or cannot be located.

Our support for this legislation is based in part on the detailed investigation of health conditions which we have been carrying on at the DoE plant near Cincinnati. DoE has shown that it cannot or will not adequately protect the workers there, and at the very least, responsibility for epidemiology studies should be placed in an independent agency, such as the Department of Health and Human Services, which has expertise in the study of public health questions. Because of the past record of DoE in failing to adequately protect and inform workers and community

people near their facilities in Ohio and Tennessee, there is now great skepticism of any health report originating with DoE, especially those which suggest that there is little hazard. These doubts are not always correct, but they are well-founded, in the sense that they are based on a confirmed history of inadequate information and inadequate protection of workers and the community. I am not arguing that every report coming from DoE is incorrect, but that because I have confirmed that past DoE behavior is clearly unsatisfactory, as a result the workers and public have good reason to be skeptical. The only way to improve public confidence in future health studies is to transfer responsibility to an agency independent of DoE influence.

I will now elaborate on the details of past and current hazards at the Fernald, Ohio facility, and the very inadequate control the DoE has exercised over their contractors in health and safety matters. The DoE has had in place a mechanism to identify problems, but this process has apparently been toothless, since identified problems have remained uncorrected for years. This continuing pattern of inadequate attention to health and safety concerns is the basis of the public lack of confidence in DoE.

DoE has a program of periodically sending staff persons from Oak Ridge to their Fernald, Ohio facility to conduct appraisals of the health physics and industrial hygiene practices of their contractor firms. Following my comprehensive tour of the FMPC in August 1985 I asked for and received several of these past appraisals. Some of the recommendations made by the DoE industrial hygienist were similar to recommendations which I made following the 1985 tour. For example, a 1981 DoE appraisal recommended that the industrial hygiene monitoring program be expanded to enable a true assessment to be made of various chemical and physical hazards other than airborne uranium. Four years later this had clearly not been done, since the DoE contractor was unable to respond adequately to my inquiry about acid mists in several areas of the plant. They claimed that they had not had a large enough industrial hygiene staff to undertake this sampling. This inadequate staffing is another deficiency noted by DoE in their 1983 appraisal but still not addressed by mid-1985. While DoE has thus had in place a mechanism to identify problems, they have been very slow to act to make changes that actually protect workers. At this plant there is a system to identify uranium-exposed workers by measuring uranium in their urine, but they have not tried to determine how people have been exposed and make changes to prevent dust releases.

In the design and carrying out of the epidemiology studies at the Oak Ridge and Fernald plants, the DoE has shown little interest in making use of the results to protect and inform workers and the community. DoE has conducted many studies on the health effects of radiation, but the design of their research has often been unfocused and unable to identify problems which may be present. Each of these workplaces is a very diverse place with different exposures from one area to another.

Some DoE studies have evaluated large worker populations but have failed to narrow down the population to look at whether the most heavily exposed subgroup is suffering excess disease. By studying large populations where most are not exposed, the good health experience of the majority will mask disease which may be present among an exposed minority. Studies must be designed to identify and evaluate these subgroups, since we know there are still high exposure jobs, and we must find out as soon as possible the magnitude of the health effects.

For example, workers are still exposed to airborne uranium, and its effects need to be studied in a way which can evaluate whether the standard now used by DoE is adequate. Many old standards like this one have subsequently been found not to protect workers health. Until recently workers in Plant 1 at the Fernald facility have been exposed to levels of airborne uranium far above this standard; in other areas workers are exposed to levels slightly below the standard, and they need to know if their health is protected by this limit on airborne uranium.

One widely discussed DoE study of the Fernald facility, by Jerome Wilson in 1983, lumps all chemical operators into the same exposure class (based on occupational title). Their exposures at work are in fact quite varied, depending on in which part of the facility they work. Little wonder, then, that this study found no relation between uranium exposure and increased disease. This study did find an overall increased rate of non-malignant respiratory disease, but DoE failed to take the initiative to inform workers of these results. They learned indirectly via a conference presentation by the author.

Other Doe studies, including a 1984 paper on the long term effects of mercury exposure at Oak Ridge, are of limited value because very crude methods of exposure evaluation have been used.

DoE contractors are still making it difficult for their workers to learn of their own radiation exposures. Just last week at a health and safety class, one of our worker students, a reactor operator at Oak Ridge, explained that he has had trouble getting information on his own recent exposures.

In summary, DoE has been using its substantial resources to practice 'ivory tower epidemiology' - oblivious to public needs and failing to carry out studies which can resolve the most important questions about the relation between exposure and health. This presents the appearance of a conflict of interest, since the primary work of DoE is research and production of nuclear materials. In order to restore public confidence in the scientific basis of radiation protection standards, it is essential that responsibility for health studies of the effects of radiation be put in an agency whose SOLE responsibility is public health - such as the Department of Health and Human Services.

NLO, Inc.

A SUBSIDIARY OF NL INDUSTRIES, INC.

P. O. BOX 39158 CINCINNATI, OHIO 45239

PHONE: AREA CODE 513-738-6200

October 17, 1985

SUBJECT: REPLY TO SECOND UNION REQUEST FOR INFORMATION

TO: Thurmen B. Wenzl

FROM: R. B. Weidner

REFERENCE: Letter, Thurmond B. Wenzl to R. B. Weidner, dated August 20, 1985

The following Tables 1 through 8 and Attachments A-1 through A-62 and B-1 through B-5 provide responses to your six part request for information contained in your August 20, 1985 letter. In those cases where air sampling information is unavailable, as in question 2 concerning Plant 2/3 and question 4 concerning oil mist, the information will be sent as soon as it is obtained and analyzed. It is hoped that this will provide sufficient useful information for your needs. Any questions about the data should be directed to me.

R. B. Weidner

WHM/whm

cc: R. M. Spenceley
R. W. Weidner
W. J. Grannen
D. A. Fleming
S. L. Hinnefeld (w/o. attach.)
W. H. Mengel (w/o. attach.)

Question 1: Recent (1984 and later) personal and area air monitoring results

TABLE 1 - Plant 1: the small pulverizing (Fitz) mill for uranium dioxide

Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
07-09-84	A	145	749	841
		115	1590	
10-16-84	B	175	2580	3410
		175	6520	
10-25-84	C	90	2270	1580
		156	2010	

			Geometric Mean =	1650

D.E. limit is 220!

No recent area samples were collected at this job.

TABLE 2 - Plant 2: for the orange oxide gulping, milling, and drumout stations

Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
03-15-84	D	98	375	410
		120	687	
03-15-84	E	92	72	54
05-03-84	F	136	87	65
06-08-84	G	105	69	52
08-21-84	H	78	112	79
		134	102	
08-21-84	I	144	581	309
		86	129	
02-28-85	J	220	14	10

			Geometric Mean =	78

No recent area samples were collected at this job.

TABLE 3 - Plant 4: air sampling results at all locations

Location	Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
SE UF4	02-16-84	K	139	180	159
Packout			123	248	
Station	03-27-84	L	129	75	94
Operator			160	166	
	08-20-85	M	107	48	42
			103	65	
	10-17-84	N	98	86	139
			144	252	
	01-22-85	O	195	192	144
	02-12-85	P	166	5	4
	04-18-85	Q	193	48	36

				Geometric Mean =	57
SW UF4	08-20-84	R	99	116	68
Packout			114	69	
Station	01-22-85	S	185	42	32
Operator	02-20-85	T	162	253	190
	02-20-85	U	160	10	8

				Geometric Mean =	43
NW UF4	08-20-84	V	75	78	100
Packout			96	176	
Station	10-01-84	X	155	689	335
Operator			106	91	
	10-17-84	Y	128	101	75
	10-17-84	Z	98	102	75
	04-24-85	AA	170	65	49

				Geometric Mean =	98

TABLE 3 (contd.)- Plant 4: air sampling results at all locations

Location	Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
Chemical Reactor Operator	03-27-84	AB	88	46	23
	09-13-84	AC	124	19	
			105	338	146
	02-22-85	AD	120	68	
	04-18-85	AE	203	35	26
			187	242	182
				Geometric Mean =	63
Bank 7 Drumming Station Operator	03-27-84	AF	105	478	379
			90	536	
Utility Operator	02-22-85	AG	208	6	5
East Drum Dumper	03-27-84	AH	150	266	342
	08-20-84	AI	110	715	
			101	175	318
	10-01-84	AJ	91	699	
			101	254	144
	10-17-84	AK	64	94	
			138	329	509
	01-18-85	AL	107	1130	
	04-24-85	AN	295	307	230
			172	479	359
				Geometric Mean =	295

No recent area samples were collected at these Plant 4 jobs.

TABLE 4 - Plant 5: the saws in "B" area

Location	Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
E Saw and Separation Operator	02-08-84	AO	102	57	37
			212	39	
	02-08-84	AP	105	59	44
			120	59	
	04-07-84	AQ	93	80	41
			115	35	
	04-23-85	AR	95	214	161
	08-22-84	AS	147	54	40
			143	52	
	08-22-84	AT	147	67	31
			142	14	
	09-15-84	AU	128	32	24
			125	33	
	09-26-84	AV	140	I0	20
			90	51	
	10-30-84	AW	144	32	24
	12-06-84	AX	118	43	20
			125	12	
	07-03-85	AY	162	25	18
			75	23	
	07-10-85	AZ	182	26	20
	07-10-85	BA	127	14	11
	08-19-85	BB	163	32	16
			127	8	
	09-04-85	BC	152	24	15
			124	15	

				Geometric Mean =	27

TABLE 4 (contd.)- Plant 5: the saws in "B" area

W Saw and Separation Operator	04-07-84	BD	88	44	31
			105	38	
	04-24-84	BE	105	37	28
			116	37	
	10-31-84	BF	128	37	24
			141	28	
	12-07-84	BG	134	10	8
			152	12	
	04-06-85	BL	135	16	12
	07-03-85	BM	149	11	8
	07-04-85	BN	160	15	14
			122	23	
	07-05-85	BO	158	22	30
			133	60	

				Geometric Mean =	17
N Scrap Saw Operator	04-23-84	BP	107	29	28
			131	43	
	08-22-84	BQ	152	17	13
	09-26-84	BR	108	2	22
			139	50	
	10-30-84	BS	150	26	15
			134	14	
	12-07-84	BT	129	10	5
			140	3	
	02-11-85	BU	190	4	3
	07-07-85	BV	120	55	24
			153	14	
	07-08-85	BX	90	25	22
			215	32	
	07-09-85	BY	120	48	20
			273	18	
	07-09-85	BZ	216	32	24
	07-09-85	CA	140	7	7
			138	12	
	07-10-85	CB	128	17	12
			196	16	
	07-10-85	CC	208	17	19
			120	40	
	07-10-85	CD	118	17	15
			207	22	
	07-11-85	CE	115	17	13
	07-11-85	CF	110	25	17
			203	21	
	07-12-85	CG	70	17	12
			215	16	

				Geometric Mean =	14

TABLE 5 - Plant 6: the B & O Cutoff Lathes

Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
02-07-84	CH	150	7	5
		122	5	
04-06-84	CI	139	11	8
09-04-84	CJ	120	15	13
		94	19	
09-21-84	CK	115	17	17
		122	27	
10-12-84	CL	133	22	17
		126	24	
10-12-84	CM	125	8	19
		138	41	
11-09-84	CN	175	5	8
		111	19	
11-09-84	CO	113	255	82
		167	10	

			Geometric Mean =	14

No area samples collected at this job.

TABLE 6 - Plant 8: Rotary Kiln

Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)	
01-16-84	CP	128	211	216	
		120	369		
03-23-84	CQ	129	52	354	
		92	1060		
03-23-84	CR	119	147	90	
		128	96		
06-07-84	CS	150	306	230	
06-07-84	CT	142	51	38	
09-06-84	CU	106	57	41	
		80	51		
10-03-84	CV	167	377	196	
		166	146		
11-26-84	CW	161	89	48	
		90	20		
01-29-85	CX	239	423	257	
		108	165		
02-04-85	CY	160	5	4	
02-08-85	CZ	232	237	178	
02-20-85	DA	140	64	48	
05-01-85	DB	250	29	22	
			Geometric Mean =	79	

No recent area samples were collected at this job.

TABLE 7 - Plant 9: LeBlonde Rapid-Bore, North Duomatic, and Gisholt 5L Lathes

Location	Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
Rapid-Bore Lathe	07-31-84	DC	138	15	8
			120	7	
	10-19-84	DE	345	15	11
	11-16-84	DF	115	24	12
			116	8	
	12-18-84	DG	135	49	27
			120	22	
	12-18-84	DH	120	15	15
			129	24	
	03-18-85	DI	287	17	13
				Geometric Mean =	13
North Duomatic Lathe	02-27-84	DJ	135	33	25
	03-16-84	DK	116	4	20
			128	47	
	04-18-84	DL	95	114	86
	04-26-84	DM	130	44	29
			149	33	
	08-30-84	DN	102	37	31
			110	45	
	09-20-84	DO	150	30	23
	10-22-84	DP	153	76	67
			115	107	
	11-19-84	DQ	155	187	69
			182	12	
	12-17-84	DR	162	96	72
				Geometric Mean =	41

TABLE 7 (contd.)- Plant 9: LeBlonde Rapid-Bore, North Duomatic, and Gisholt 5L Lathes

Location	Date	Employee	Time (min)	Uranium Conc'n (ad/m/m3)	TWA Uranium Conc'n (ad/m/m3)
Gisholt 5L Lathe	02-21-84	DS	115	209	159
			86	217	
	04-18-84	DT	89	165	124
	06-01-84	DU	98	209	163
			105	226	
	08-01-84	DV	97	226	88
			102	15	
	10-18-84	DX	130	163	148
			142	230	
	11-16-84	DY	115	48	29
			126	30	
	12-18-84	DZ	120	16	20
			126	38	
	03-07-85	EA	164	309	232

Geometric Mean = 93

Question 2: No recent personal or area air samples have been collected in the Metal Dissolver Building or at the Denitration operation for nitric acid mist or NOx. At present, this facility is not operating; however, when operations resume, samples will be taken using long-term Draeger tubes, and a summary of results will be sent to you at a later date.

TABLE 8 - Plant 4: Area Samples for Hydrogen Fluoride (HF)

Location	Date	Time (min)	HF Conc'n (ppm)
3rd Flr. HF Area	12-16-83	183	0.9
"	01-03-84	165	9.8
"	01-03-84	62	3.5
	01-03-84	231	0.2
619' Level Between Cocoa Screw #8 + #9	02-06-84	360	0.0

TABLE 9 - Plant 6: Personal Samples for NOx at Chip Washing and Scrap Pickling

Location	Employee	Date	Time (min)	NO2 Conc'n (ppm)	NOx Conc'n (ppm)
Chip Washing Operator	EB	10-21-83	83	0.6	NA *
Scrap Pickling Operator	EC	04-04-83	102	0.6	5.1
	ED	04-05-83	95	2.4	6.9

* - Not analyzed for the contaminant in this column

TABLE 10 - Plant 9: Personal and Area Samples for NO2, NOx, and HNO3 at the Zirnlo

Date	Employee	Time (min)	NO2 Conc'n (ppm)	NOx Conc'n (ppm)	HNO3 Conc'n (ppm)
03-01-83	EE	330	0.5	NA *	NA
04-07-83	EF	112	3.0	NA	NA
04-08-83	EG	96	0.4	4.5	NA
02-28-83		155	2.0	10.2	NA

* - Not analyzed for the contaminant in this column

Question 3: Summary of beta and gamma (B/Y) wrist dosimetry for employees handling blanks and cores in Plant 6 measured during July 1985

TABLE 11 - Wrist (B/Y) Dosimetry of Plant 6 Employees During July 1985

Location	Employee	Right Wrist (mrem B/Y)	Left Wrist (mrem B/Y)
B & O Cutoff Lathe	EH	801	774
	EI	609	708
Chip Briquetter	EJ	645	483
	EK	186	201
Chip Washer	EL	996	1095
Cross Machine Stamper	EM	1032	1662

Explanation of Terms Used in Tables:

Term	Description
Date	Date on which sample was collected.
Employee	Employee's name coded so as to protect confidentiality.
Time	Length of sampling time in minutes.
Conc'n	Concentration of airborne contaminant measured by one sample.
TWA Conc'n	Time-Weighted Average Concentration computed by: $\frac{C_1 \times T_1 + \ldots + C_n \times T_n}{T_1 + \ldots + T_n} \times \frac{6}{8}$ TWA concentrations are computed for all BZ samples on the same employee for the same contaminant on the same job on the same day. The factor of 6/8 is used to assign a zero concentration for the two hours each day that the employees are not in the work area; i.e. lunch, showers, etc. If the total sampled time in a given day is less than 6 hours, this formula extrapolates the measured concentration to 6 hours.
Maximum TWA Airborne Levels	Uranium: this is expressed in units of alpha disintegrations per minute per cubic meter of air ($ad/m/m^3$). DOE limit for insoluble 0.7% enriched uranium is 220 $ad/m/m^3$. Hydrogen fluoride: American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV's) TLV = 3 parts per million (ppm) Nitrogen dioxide (NO_2): TLV = 3 ppm Nitric oxide (NO): TLV = 25 ppm Nitrogen oxides (NO_x): no published limits exist
G.M.	Geometric mean of TWA concentrations. A measure of central tendency of a log-normal distribution comprised of TWA concentrations.

Question 4: Mineral oil mist has never been sampled at the Plant 9 LeBlonde Rapid-Bore lathe; however, in response to your request, both breathing zone and general area samples were collected from 09/17-21/85 along with a bulk oil sample. These have been sent to an outside analytical laboratory for analysis by NIOSH method S-272. A summary of these results will be sent to you at a later date.

Question 5: Attached are photocopies of Department of Energy Industrial Hygiene and Health Physics appraisals for 1982 and 1983 (Attachments A-1 through A-62). The 1983 appraisal was the most recent routine appraisal.

Question 6: Attached are photocopies of Material Safety Data Sheets on Beacon K-9 heat treating oil and Sun Seco soluble cutting fluid (Attachments B-1 through B-5).

EXPOSURE STUDY OF PLANT 5 PERSONNEL TO AIRBORNE RADIOACTIVE DUST

by

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National Lead Company of Ohio

February 1, 1966

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Department

National Lead Company of Ohio
Cincinnati, Ohio
Contract No. AT(30-1)-1150

ABSTRACT

This is a study of the exposure of Plant 5 Production personnel to airborne radioactive dust during the period July through December 1965. Results of this survey indicate that on a daily weighted exposure (DWE) basis, 3 of the 38 persons in "A" Area and 17 of the 74 persons in "B" Area are potentially exposed to air dust levels in excess of 100 alpha disintegrations per minute per cubic meter of air, The National Lead—Company of Ohio Concentration Guide (NCG) for airborne radioactive contamination.

The average DWE has decreased from 2.3 NCG in 1964 to 0.9 NCG in 1965. This decrease can be attributed to the following improvements made to equipment and improved ventilation. (1) Ventilation Revisions - East Breakout Station;(2) Restoration of the East Separation Booth; (3) Revisions to West Breakout Station; (4) West Capping Stations enriched operation improvement; (5) Additional ingot cooling installation, West Separation Booth; (6) West Breakout Drumming Station revisions; (7) Ventilation revisions at the Egg Cup Lathe.

Included in this report is a discussion of operations and sources of dust contamination as well as recommendations for the alleviation of existing airborne dust sources.

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INTRODUCTION

The purpose of this survey is to provide Plant 5 supervision with information relative to the degree of change of air dust levels from year to year. The survey also provides the Industrial Hygiene & Radiation Department with current data for maintaining a record of individual personnel exposures.

It is hoped that through the discussion and recommendations contained herein that Plant 5 will be able to better control their airborne dust problems.

METHODS

Air dust samples were collected on Whatman #41 filter discs by pulling a metered quantity of air through the filter for a measured amount of time. The samples were analyzed by standard radioactive counting methods, using scintillation counters. Exposures to airborne radioactive dust were calculated by utilizing the time spent in an area or at an operation together with the results of the air dust samples obtained in the area or at the operation. The time factors were supplied by Plant 5 supervision.

The fact that respirators are worn for some of the operations was not taken into consideration in calculating exposures. It can be assumed that exposures of those persons making proper use of prescribed respiratory protection were materially reduced from the calculated values.

SUMMARY OF DATA

The Plant 5 average DWE has decreased from 2.3 NCG in 1964 to 0.9 NCG during 1965, the average "A" Area DWE is 0.7 NCG this year compared to 1.0 NCG in 1964. The average "B" Area DWE also showed a decrease, from 3.2 NCG in 1964 to 0.9 NCG for this year. Of the 38 "A" Area employees, 3 are potentially exposed to air dust levels above the NCG on a DWE basis as compared to 17 of 74 "B" Area employees.

Table I-A lists the DWE's for the "A" Area employees of which 8% exceed the NCG.

Table I-B lists the "B" Area DWE's; of the 74 employees, 22% are potentially exposed to air dust levels above the NCG.

Table II-A and II-B list the air dust levels at the operations and areas throughout the "A" Area and "B" Area, respectively.

Appendix I contains the job exposure evaluation sheets.

Appendix II contains the ventilation data for Plant 5 ventilation systems.

CONCLUSIONS

This survey shows that the average DWE for Plant 5 Production Personnel has decreased for the third consecutive year from 3.0 NCG in 1963 to 2.3 NCG in 1964 to 0.9 NCG in 1965. This decrease can be attributed to the completions of several CP's and Job Order Requests.

Although the average DWE in Plant 5 has decreased in 1965, there is still room for improvement. At present there are eight potential DWE's that exceed the NCG and are of primary concern. These are east and west bottom furnace operator, the "A" and "B" Area residue operator, the east and west saw operator, the east charge operator and the west delidding operator.

The number of employees in Plant 5 have also decreased from 129 in 1964 to 112 in 1965.

It should be mentioned that Plant 5 supervision has been most co-operative with the Industrial Hygiene & Radiation Department during the year 1965. Through this co-operation, various operations which exceeded the NCG, have been reduced and are now below the NCG.

RECOMMENDATIONS

The following Recommendations prefaced with an "E" require maintenance or engineering service and need not necessarily involve work beyond Job Order Requests.

E-1. Consider a re-design of the east and west mold tank cleaning station. Although ventilated, the dust levels remain well above the NCG when the mold tanks are cleaned.

E-2. Repair the Hoffman shakers and keep them in good repair at the primary for G-5-249 and the secondary for G-5-254.

E-3. Repair the valves on the Hoffman downcomers to eliminate leaks at G-5-247, G-5-250, G-5-261 (secondary), G-5-258 (primary) and G-5-259 (secondary).

E-4. Repair leaks at the jolter bins and the overhead conveyor.

E-5. Investigate and determine how long the ingots should be allowed to cool in the tunnels provided, include this in the appropriate procedure and comply with it.

E-6. Continue to maintain an adequate furnace pot air purging system at the breakouts and insure that it is used consistently.

E-7. If the graphite crusher is to be used, eliminate the leaks, provide an opening for an airline respirator at the graphite drumming station, consider enlarging the crusher drumming station to allow the drums to be lidded inside the enclosure, and provide adequate ventilation.

TABLE I - B

"B" AREA

Job Classification	No. of Men	1962	1963	1964	1965
East Bottom Furnace	3	2.8	1.5	5.8	9.0
Residue - 1st and 2nd Shifts	2	3.3	1.8	23.	2.3
West Bottom Furnace	3	2.8	1.5	5.2	1.3
West Circular Saw	3	-	-	0.7	1.2
East Circular Saw	3	0.8	0.3	1.5	1.2
East Charge Station	3	0.7	3.2	4.1	1.1
Contaminated Lathe	1	-	2.8	2.4	0.8
Pump Man	1	0.4	0.5	1.1	0.6
Shift Foreman	4	0.6	0.7	0.8	0.6
Residue Operator - 3rd Shift	1	3.3	0.8	4.3	0.6
Area Foreman	1	0.5	0.8	0.8	0.6
East Top Furnace	4	0.6	1.3	0.8	0.6
Coal Car	1	-	-	-	0.6
Mold Reconditioning	3	1.2	1.2	1.2	0.5
Shipping	2	0.2	0.3	0.4	0.5
Fork Truck	5	0.3	0.2	0.4	0.5
West Burnout	3	0.6	1.3	1.5	0.5
East Burnout	3	0.6	1.3	2.1	0.5
East Separation Booth	3	-	96.3	26.	0.4
West Charge Station	3	0.7	3.2	4.1	0.4
West Separation Booth	3	14.4	0.9	1.9	0.4

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TABLE II - B

"B" Area

Operation or Location	Type Sample	1962	1963	1964	1965
During West Crucible Charging Operation	GA	0.6	3.5	2.0	0.6
West Crucible Charging Operation	BZ	1.1	4.2	2.2	0.5
Graphite Lathes					
Changing molds at the Contaminated Lathe	BZ	-	-	-	1.8
Operating the Contaminated Lathe	BZ	-	-	1.4	0.8
Operating the Cup Lathe	BZ	-	1.7	3.8	0.7
During Operation of the Cup Lathe	GA	-	0.7	1.2	0.3
During Operation of the Contaminated Lathe	GA	0.6	1.5	1.1	0.2
Graphite Shop	GA	0.1	0.2	0.2	0.1
Mold Reconditioning					
Coating Egg Cups	BZ	-	-	5.6	1.1
Cleaning and Coating Molds	BZ	2.8	3.0	1.3	0.6
Mold Reconditioning	GA	0.7	1.0	1.2	0.6
Saws and Sharpener					
Removing Sample from West Saw and Stamping	BZ	0.5	1.9	0.3	6.3
Removing Sample from East Saw and Stamping	BZ	-	-	-	5.9
Renoving Ingot from West Saw Weighing and Stamping	BZ	0.5	0.9	0.3	5.0
Removing Ingot from East Saw Weighing and Stamping	BZ	-	-	-	4.8
Setting up Ingot at the West Circular Saw	BZ	0.5	2.5	1.1	2.0

NATIONAL LEAD COMPANY OF OHIO
JOB EXPOSURE EVALUATION

Survey Period July - December

Operator Residue 1st and 2nd shifts

Building Plant 5

Shifts/Day 2 Men/Day 2

Process Area B Area

TYPE OF SAMPLE	AREA OR OPERATION	TIME PER SHIFT (T)	NO. OF SAMPLES	CONCENTRATION			AVERAGE NCG (C)	T. x C.
				HIGH	LOW	AVERAGE		
BZ	Emptying Dust Collectors*	40	3	130	100	110	1.1	44.0
BZ	Checking Hoffmans*	60	3	900	400	566	5.7	342.0
BZ	Changing Drums at Hoffmans**	20	3	4,400	2,000	2,833	28.	560.0
BZ	Cleaning Filter Press*	20	5	320	100	216	2.2	44.0
BZ	Separating and Vacuuming Ingots	80	3	110	34	74	0.7	56.0
BZ	Separating Booth Area	40	4	64	30	38	0.4	16.0
GA	"E" Area, General	125	127	640	4	87	0.9	112.5
GA	Smoking Area	20	3	71	53	60	0.6	12.0
GA	North Washroom	20	3	55	16	34	0.3	6.0
GA	Washroom	20						
GA	Travel Time	20	24	5	N.D.	2	0.1	2.0
GA	Shower and Change	35	24	59	1	12	0.1	3.5
GA	Cafeteria	30	12	9	N.D.	2	0.1	3.0

N.D. = NON-DETECTABLE

* = A dust-type respirator should be worn when performing this operation.

** = An air supplied respirator should be worn when performing this operation.

= National Lead Company of Ohio Classification Guide

$\Sigma(T)$ 510

$\Sigma(T \times C)$ 1201.0

$\frac{\Sigma(T \times C)}{\Sigma(T)}$ = 2.3 N.C.G.

TESTIMONY OF
SAMUEL T. FIFE
ICWU LOCAL 715 and
ATOMIC TRADES AND LABOR COUNCIL
OAK RIDGE, TENNESSEE

BEFORE THE
HOUSE SUBCOMMITTEE ON
ENERGY AND ENVIRONMENT
NOVEMBER 13, 1985

Good morning, Mr. Chairman, and Representative Wirth. My name is Samuel Fife. I am chief steward for the International Chemical Workers Union Local 715, and Health and Safety Representative for the Atomic Trades and Labor Council, representing 4400 hourly workers at Oak Ridge National Laboratory and Y-12 Nuclear Weapons Facility in Oak Ridge, Tennessee. Besides representing these working people, I am here, along with Brother Pat Kelly, representing over 25,000 DOE plant hourly workers nationwide, all of whom have endorsed Mr. Wirth's bill, H.R. 1287, through their representatives' participation in the National Atomic Labor Health and Safety Conference. There are over 60,000 hourly workers (120,000 total) at DOE facilities across the country that are directly affected by this legislation; in a broader sense, over 2½ million people work around radiation and are regulated by the Government--directly affected by the mismanagement and conflict of interest in DOE's nuclear health studies program.

I endorse completely the statements of Brother Kelly and would like now to add my own experiences with DOE-funded and supervised health studies. I need to emphasize here at the beginning of my presentation, that we think studies are important. As the primary subjects of these human studies, workers should be kept informed of <u>all results</u>, even "inconclusive" ones. Workers should also be given oversight roles in selecting the design of the studies and in monitoring the studies' progress.

Removal of DOE from the funding and supervision of epidemiological research is necessary for developing objective radiation and hazardous chemical standards and protections in the future. <u>It will perform a service for both sides of the radiation health effects debate.</u>

A different matter is where there are exposures to KNOWN cancer-causing substances at work. The union's priority is to reduce exposures. We oppose the wait-and-see attitude of DOE which has postponed all action for 40 years until studies are "completed". By the time they are complete, it may be too late to do anything except bury the dead.

How much has DOE been willing to work with labor by informing us about the existence of these studies and involving us in the monitoring of these studies? The short answer is that they have never been willing, and have never begun to do so with out much prompting and pushing and shaming by the unions. My own experience with Oak Ridge Associated Universities (ORAU) over the last two years is a case in point.

ORAU is a DOE prime contractor and has been since 1946 (it was called Oak Ridge Institute for Nuclear Studies until the mid-1960s). Most of their budget has come from DOE to do clinical and statistical studies on workers and the general public, using isotopes and drugs provided by DOE, and having access to workers' medical records and exposure data with permission from DOE. Since the mid-1970s, ORAU has had authority over the DOE Health and Mortality Study on 600,000 plant workers; the Radiation Accident Registry; the experimental drug DTPA Registry; and, at various times, clinical studies and follow-up on workers.

My Council asked for me to be appointed as a labor representative on the Oak Ridge Associated Universities Human Studies Committee which oversees all "human uses" of radioisotopes. After I had been promised this position by Robert Goldsmith of DOE's Office of Health and Environmental Research (OHER)--and, as he put it--"even if Dr. Karl Hübner, the chairman of the Committee had to resign to make an opening"--Dr. Hübner wrote my Council a letter calling labor a "special interest group" and so would not be allowed to sit on the very committee that passes on worker experimentation.

The DTPA experimental drug program run by ORAU for DOE illustrates very well the dangers of the working man being kept off this Committee and, more generally, out of the oversight process of these studies.

Another example is the case of the Transuranic Registry, or Body-snatching

Program, run by Hanford, Washington's ORAU-equivalent, Hanford Environmental Health Foundation/Battelle Northwest.

We have also found numerous examples on AEC/DOE worker-human experimentation within secret records that we asked for in May, 1985 through Representative Markey's Subcommittee on Energy, Conservation, and Power; the release of these documents have been held up for an as yet unknown reason. In the documents are examples of workers being "volunteered" to be gratuitously and purposefully dosed with harmful radioisotopes in order to be given DTPA "just to see what will happen".

What, regarding DOE health studies, needs to be restructured immediately? As Brother Kelly's testimony points out, many self-studies and verifications, not to mention years of the DOE weasel guarding the chicken-coop and providing the head count of the chickens--all of this real conflict of interest needs to be corrected. The atomic labor movement has put this as a top priority and will be working hard to accomplish this comprehensive task.

But what about immediately? We think that our interests and the interests of the general public would be well-served if all federal monies to study nuclear health effects were taken from DOE and its prime contractors, and all supervisory and advisory responsibilities for these studies. The responsibilities should be given to another federal agency that will have no problem working with the people they are studying.

It is also very important that all record systems involved with these health and safety studies be made the property of the agency that receives the authority to do the research. Otherwise, there will be jurisdictional problems. DOE has stated to individual workers and unions that, in fact, DOE owns all records on workers--medical, exposure, insurance, and registry information. Currently, an individual worker can file for his/her records at work and wait as long as 3 months to get what in our opinion is incomplete data. Unions do not have the right to file for their members records, due to DOE's interpretation of the Privacy Act. Meanwhile DOE allows ORAU and other studiers to see them and possess them as a so-called "routine use" exception to the Privacy Act, i.e., without worker or union permission. ORAU, for one, readily admits that it depends

on DOE "permission" to use these records to do the studies. We do not want the new agency to have to depend on DOE "permission"--we want the agency to have the right to these documents immediately, as well as access to past records that have been collected by DOE. Without this right, the continuity of these studies will be seriously jeopardized.

DOE Record Systems in question: (kept under authority of 5 USC 301)
DOE-33: Personnel Medical Records
DOE-35: Personnel Radiation Exposure Records
DOE-36: Statistical Analysis Using Personnel Security Questionnaire (Health and Mortality Studies)
DOE-38: Occupational and Industrial Accident Records
DOE-40: Contractor Employee Insurance Claims
DOE-41: Legal Claims
DOE-67: Participants in Experiments, Studies, and Surveys
DOE-71: Radiation Accident Registry
DOE-73: US-DTPA Registry
DOE-76: Calif, Nevada, Utah Milk Directory
Add to this the Transuranic Registry mentioned above, and all "special-case" files relating to all exposed personnel.

We the workers are not afraid of the criticism leveled at this legislation by DOE and its prime contractors: that to change agencies "in mid-stream" will hold up these studies and be against the interest of the worker and the public. We say better a small hold-up now than to continue under the current practice of having DOE study us to death, not knowing about it until too late to have any input into design or priority of study, having them never draw real conclusions, and having them never act on any results to correct health hazards at work.

Oak Ridge
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Post Office Box 117
Oak Ridge, Tennessee 37830

Medical and
Health Sciences
Division
615/576-3480
FTS/626-3480

March 28, 1985

Mr. John C. Taylor
President, Fernald Atomic
Trades and Labor Council
NLO, Inc.
P. O. Box 39158
Cincinnati, OH 45239

Dear Mr. Taylor:

This is in response to your letter of January 27, 1985, to Dr. Carl Shy, University of North Carolina (UNC) concerning your obtaining exposure data and other documents pertaining to epidemiologic studies of present and former workers at the Fernald Feed Materials Plant.

I must explain that all data relating to individuals ever employed by the Department of Energy (DOE; and its predecessor agencies) and DOE contractors, including NLO, Inc., are government records in the custody of ORAU protected under Federal law and can be obtained only from DOE.

Our research protocols for epidemiologic studies involving specific populations of DOE workers follow the methodologies described in the overall study protocol as presented publicly by Dr. Shy in 1982; a copy of this document is attached for your information. In the interest of conducting our research independently, we do not submit protocols for review or approval by any of the parties to the studies, i.e., DOE, the contractor, and the employees. Specific protocols are described in written reports of study results prepared for publication in scientific journals.

We are continuing to work to identify and develop additional mechanisms whereby we can effectively inform the DOE contractors and their employees on an on-going basis about the status of our epidemiologic studies of employees at the various facilities included in the Health and Mortality Study. We shall continue our practice of submitting reports of results of completed studies for publication to peer reviewed scientific journals and of giving oral presentations at professional meetings as evidence of the status of the various studies that are in progress. Dr. C. C. Lushbaugh, then chairman of the Medical and Health Sciences Division, met with representatives of the union and the employer at the Fernald plant in June 1984 to discuss our work on that population. We have recently participated in public meetings in Oak Ridge and in a regularly scheduled employee health and safety meeting at the

Oak Ridge National Laboratory (ORNL). We have been invited to expand this latter activity to include the other plants in Oak Ridge and anticipate presentations at meetings of the plants' company/union advisory health and safety committees from time to time. We recently met with Mr. Sam Fife, Union Representative for Health and Safety, Company/Union Committee, ORNL, to brief him on the Health and Mortality Study with particular reference to studies of employees at the Oak Ridge plants. We plan to prepare written summaries of reports of study results, including any concerning Fernald plant employees, that are accepted for publication in a peer reviewed scientific journal; these summaries will be available for distribution to employees prior to the publication of the scientific report.

Sincerely,

Shirley A. Fry, M.B., B.Ch., M.P.H.
Director
Center for Epidemiologic Research

SAF:jj

Enclosure

Statement of

Mary L. Walker
Assistant Secretary for Environment, Safety and Health

U.S. Department of Energy

Before the

Subcommittee on Energy, Nuclear Proliferation
and Government Processes
of the
Committee on Governmental Affairs
U.S. Senate

June 17, 1986

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the role of my office in the Department of Energy (DOE) and to assure you of Secretary Herrington's personal commitment to a quality environment and to the safety and health of our workers and the public. This commitment supports the Department's view, as expressed by Dr. Trivelpiece, that it is both unnecessary and unwise to transfer certain authorities, as envisioned in S. 525, the Radiation Reorganization Act of 1985, from the Department of Energy to another agency.

Before proceeding, I would like to emphasize the role of the Office of Environment, Safety and Health (ES&H), which I will discuss in more detail in a moment, as compared to the role of the Office of Energy Research, in regard to environment, safety and health matters. The role of ES&H is to assure the adequate protection of the environment and the health and safety of our workers and the public. The role of the Office of Energy Research is to study the health and safety of DOE workers and the public living near our facilities to discover if working in or living near these facilities may affect people's health, and if so, to identify the specific cause. The Department believes the epidemiological research function is important to monitoring health and safety effects on our workers and the public and in setting standards for future operations.

In the Secretary's environmental policy statement of January 8, 1986, he indicated that the Department is "firmly committed" to

assuring public health, and that all activities of DOE should "recognize and reflect this concern and public trust." This commitment is reflected in several new initiatives, announced by the Secretary last September, which are designed to strengthen the environment, safety and health function within the Department of Energy. I would like to highlight these initiatives for you and report on some of the progress we have made in implementing them.

First, let me outline for you my responsibilities as the principal advisor to the Secretary on environmental, safety and health matters. Among other things, it is my job to assure conformance of the Department's activities with all applicable environmental laws and regulations and to assure that the health and safety of workers and the public are adequately protected. That responsibility includes the identification and prioritization of environmental and safety concerns and the initiation of corrective action, where appropriate, to assure that environmental and safety risks are reduced to acceptable levels. In meeting these responsibilites, I can assure you that I share the Secretary's commitment that the protection of the environment and the health and safety of workers and the public are of paramount concern and importance to the Department.

The priority the Department places on its safety and health program, and the positive results realized from that program, are demonstrated in comparisons with the private sector. Without exception, for each year since its creation, the Department has carried out its operational missions at its approximately 225 industrial and research sites across the United States with a safety and health record that is at least two-to-three times better with respect to fatalities, injuries and illnesses than that of the private sector. I intend to make sure that this record is maintained and that improvements are made where appropriate.

Let me turn now to the new initiatives announced by the Secretary on September 18, 1985, to strengthen the environment, safety and health function within the Department of Energy. Briefly, these included:

- Consolidation and upgrading of the oversight responsibility for environment, safety and health under the new Assistant Secretary for ES&H.

- An Environmental Survey of all DOE facilities to identify Department-wide environmental problems and areas of potential risk and to prioritize corrective action.

- Technical Safety Appraisals of DOE's nuclear facilities to determine compliance with DOE health and safety requirements.

In addition, other elements of the new initiatives include: (1) revising the environment, safety, and health orders in the Department to strengthen ES&H's oversight role and responsibilities with respect to DOE operations; (2) increasing guidance activities and enhancing liaison with State and Federal agencies; (3) a more aggressive ES&H role in the development and implementation of environmental and safety policy for the Department; (4) an improved field reporting and computer assisted tracking system; and (5) enhancing the professional development of ES&H staff.

I am pleased to report that progress has been made in implementing these initiatives, as indicated in the March 1986 report of the General Accounting Office on the "Status of Department of Energy's Implementation of 1985 Initiatives." The reorganization of the headquarters ES&H function is essentially complete, and, I believe, the new ES&H office is becoming integrally involved in the operations of the Department at all levels. Field work has been started for the Technical Safety Appraisals, and planning is well underway to initiate the Environmental Survey activity in June at the Feed Materials Production Facility at Fernald, Ohio.

This background on the oversight role of ES&H in the Department of Energy, as enhanced by the Secretary's new initiatives, adds some perspective, I believe, to the view that health impact studies of nuclear activities of the Department can be performed most effectively and efficiently by DOE. For the reasons discussed below, I believe it is both appropriate, and supportive of my responsibilities as the principal advisor to the Secretary on ES&H matters, for epidemiological studies on the effects of radiation to continue to be performed within the mission of DOE.

First, let me describe my responsibilities in establishing radiation protection standards for the Department and how this responsibility is related to epidemiological studies of the effects of radiation.

ES&H is responsible for developing policies, standards, and procedures for the Department and our contractors for the protection of the safety and health of workers and the public near our facilities. Radiation standards established by my office comply with applicable Environmental Protection Agency (EPA) standards and are consistent with recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). In addition, our standards for the protection of workers and members of the public are comparable to the Nuclear Regulatory Commission (NRC) standards in 10 CFR 20.

As described by Dr. Trivelpiece, epidemiological studies supported by the Department are conducted by independent scientists and are submitted directly by these scientists for publication in scientific journals. These studies are peer reviewed and information from them may be used, together with other scientific studies from other sources, by DOE, other agencies, such as EPA and NRC, and scientific bodies, such as the ICRP and NCRP. While the results from DOE epidemiological studies are not used directly by ES&H in establishing radiation protection standards, they support the standard setting and risk assessment processes.

Much of the data and information required for DOE's epidemiological studies is identical to the monitoring data required by ES&H for compliance and protection purposes for the Department and its contractor operations. Under the Department's monitoring and reporting requirements, the Department maintains a radiation monitoring program at each of its sites to determine compliance with its safety and health protection requirements and standards. Environmental monitoring reports are prepared annually for each DOE site which summarize the results of monitoring and interpret the levels of radioactivity. Maximum radiation doses received by a member of the public and population doses received in the regional area are reported. Workers in restricted areas at DOE facilities are also monitored for radiation exposures. Radiation

exposure records for these personnel are kept at each DOE site and summary data for each site are maintained in a centralized location at the System Safety Development Center (EG&G, Idaho). I believe that maintaining the current epidemiological study function within the Department provides an efficient mechanism for the use of the data and information collected by ES&H. Transferring the epidemiological function out of the Department would create much duplication of effort and would be cumbersome to the Department.

In addition, studies conducted by the Department are sometimes used as supporting information for environmental documentation used as input to Department decisions. For example, studies funded by Defense Programs on the occupational work force and the comparison of county and state mortality rates were used as supplementary documentation for an environmental impact statement issued in 1982 for the proposed construction and operation of additional facilities at DOE's Pantex facility in Texas. Information provided by these studies may be useful to the decisionmaker in weighing the consequences of an action to workers or the public. I believe that responsiveness needed by ES&H for prioritizing such studies might be sacrificed if the responsibilities were transferred from the Department to the Secretary of Health and Human Services.

To summarize, ES&H uses the epidemiological studies from the Office of Energy Research in its activities; in turn, the Office of Energy Research benefits from the worker and public monitoring efforts that we administer. I believe it is important to have both of these functions in a single government agency for defining needs, prioritizing studies, and eliminating the duplication of effort that would occur from separating the two functions.

I hope that this information is helpful to the Subcommittee, and would be pleased to respond to any questions you may have.

Statement of Alvin W. Trivelpiece

Director

Office of Energy Research

before the

Subcommittee on Energy, Nuclear

Proliferation and Government Processes

of the

Committee on

Governmental Affairs

United States Senate

June 17, 1986

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to appear before you today to present the views of the Department of Energy on S. 525, the Radiation Reorganization Act of 1985. The Department strongly opposes enactment of this legislation because it would seriously disrupt the ongoing scientific research, be deleterious to workers' health because of this disruption, and involve substantial costs in time and effort due to the mechanics of transfer, recompetition of research grants, possible fragmentation of the program among several agencies, and duplication of effort.

The Department and its predecessor agencies have been at the forefront of pioneering radiation research for decades, have been responsible for the development of most of our current knowledge about the health effects of exposure to ionizing radiation, and have demonstrated a commitment to long-term support of occupational radioepidemiologic research. Furthermore, although there appears to be a perception that these studies might involve a potential conflict of interest, in reality there is no conflict of interest, and therefore, there is no concrete reason why the studies' transfer is warranted. Quite to the contrary, there is ample evidence that the studies have been conducted in an appropriate manner both scientifically and administratively.

In my testimony today, I would like to address the responsibilities of my Office within the Department, the reviews of DOE's radioepidemiology program which have been conducted in the past, and the issue of perception of potential conflict of interest.

The issue of DOE's role in funding radioepidemiologic research of the Department's workers is confounded somewhat by a misunderstanding of the respective roles of the Office of Energy Research, which I head, and DOE's Office of the Assistant Secretary for Environment, Safety and Health. My Office is not responsible for the operation of nuclear materials facilities, nor for the health and safety of employees in those facilities, nor for the standards which govern occupational exposures in those facilities. We are the research arm of the Department. With respect to health and safety of DOE workers and the public living near DOE plants, we are responsible only for research to discover if working in or living near the facilities may affect peoples' health, and if so, to identify the specific cause. We do not set standards, we do not perform inspections, we do not monitor compliance. We administer a health research program which includes studies of employees at national research laboratories, and I am confident that we do it well.

The Department has a proven record of concern for the safety of its workers. In 11 years of operation, the Department of Energy's national research laboratories have experienced only one fatality (excluding transportation accidents). In general, the DOE laboratory worker is 10 times less likely to sustain a fatal injury than the average U.S. worker, and also 10 times less likely to be killed on the job than off the job. The DOE laboratories experience only 2.0 recordable injury cases for every 200,000 hours of work. This is 71 percent better than the injury rate of the U.S. "all industries" average, as published by the National Safety Council. The chance of injury for a DOE national laboratory worker con-

tinues to be one-third that of the average U.S. employee. Thus, the excellent safety performance of the DOE laboratories represents an annual savings of 65,000 workdays or 275 worker-years over what would have been experienced at the private sector rate.

Despite this excellent record, there has been confusion over alleged "excess" mortality among workers at these facilities. The confusion is really a consequence of small number statistics. That is, one must realize that in epidemiologic studies, as in most scientific research, results must be examined in the light of the statistical probability that the observed sample result reflects universal reality. A coin-toss example may help to clarify this problem. If a coin were to be tossed into the air a large number of times, one would expect that the tosses will result in heads 50% of the time, and tails 50% of the time. However, if one were to toss a coin ten times, and then decide whether the coin is fair or not, based on the results of the tosses, the conclusion could be very misleading. If the tosses resulted in six heads and four tails, could one realistically call the coin unfair, even though there was a 50% "excess" of heads? Even if the results were seven heads and three tails, could one decide unequivocally that the coin was unfair? The answers to these questions most likely are - no; yet the "excesses" are 50% and over 100%, respectively. The decision might be easier if the coin were tossed 1000 times and the heads and tails results were the same in terms of percentages. Needless to say, in the epidemiologic research setting these decisions are much more difficult because one is dealing with people, and the data base can be severely limited. The same care must always be used in research involving small

sample size. Statistical testing must be done and considered in evaluating whether observed "excess" events are, in fact, real. Studies must be continued to increase sample size, and the data obtained in the original study must be combined in meaningful ways to correctly assess mortality patterns.

There is further confusion over who actually performs radiation epidemiologic studies. DOE-supported radioepidemiologic studies are performed by scientists at universities and national laboratories, rather than by Federal employees. The DOE, more than any other Federal agency, relies on these government-owned, contractor-operated (GOCO) laboratories to perform research and development related to its mission. The management and operating contract provides for a unique relationship between the Department and the contractor, designed to dedicate the technical and administrative skills of private organizations to important agency missions. Although the contractor is organizationally separate from its parent organization, it is expected to use corporate experience and practices in managing the DOE laboratory. Under the GOCO arrangement, laboratory staff work in buildings and use equipment that is goverment-owned, but they are employees of the contractor.

The question "Why not transfer the authority to conduct radiation epidemiology studies?" has been asked on previous occasions. Back in 1981, the Committee on Federal Research on the Biological and Health Effects of Ionizing Radiation of the National Research Council, National Academy of Sciences (also known as the FREIR Committee) examined this question extensively. It would be

helpful to quote the Committee's report. The Committee states, on page 10-23 et seq.:

> ..."it does not believe that reorganization per se will greatly improve the credibility of research results obtained by government agencies. Much of the opposition to DOE and other technology-promoting agencies stems not from the fact that they develop technologies, but from the fact that they develop certain technologies. Objections are voiced by citizens who abhor a dependency on nuclear weapons, the promotion of nuclear power, and the proliferation of certain types of medical devices." ... "Still others are concerned about what they perceive to be the refusal of government to provide compensation for individuals putatively exposed to harmful levels of ionizing radiation as the result of agency actions. These individuals are likely to remain skeptical of pronouncements that do not agree with their notions of justice regardless of the level of government from which these pronouncements emanate. The FREIR Committee is doubtful that the proposed structural reorganization would result in a settlement of such intensely divisive political issues."

> "Indeed, if that reorganization were to produce a recentralization of authority in ionizing radiation research, the Committee believes that the government's credibility in this area is likely to be subjected to even further questioning. Public acceptance of the results of scientific research is enhanced when the same results are generated by different groups of investigators that use different approaches and have different sources of support. The existence of the current number of agencies supporting radiation hazard research — some with the mission to promote technologies, some with the mission to regulate technologies, and some with the mission to support general scientific research — may appear disorderly, but it does have the effect of increasing the breadth of reliable information pertaining to the effects of ionizing radiation and providing the opportunity for the development of confirmatory evidence in the field."

> "Technology-development agencies such as the DOE and the DOD should be encouraged to sponsor research on the risks of exposure to ionizing radiation. These agencies should never be blind to the potential negative consequences of their endeavors. Technology development no less than technology regulation should be informed by results of research on the health effects of ionizing radiation. There are important reasons to separate functions within government, but none to restrict the acquisition of knowledge and sponsorship of research by agencies responsible for the management of the several functions."

The statement in the Congressional Record which accompanied the introduction of S. 525 referred to the Interagency Task Force on the Health Effects of Ionizing Radiation, citing its specific consideration of "...ways of expanding the role of health and regulatory agencies in the area of radiation research as a means of dispelling some public perception of a conflict between DOE's role as the primary sponsor of research into the biological effects of ionizing radiation and its roles as a developer and promoter of nuclear energy...". After studying this issue, the Task Force, on pages 101-102 of its report, recommended that:

- o NIH assume a lead role in funding research into the biological effects of ionizing radiation.
- o Other health-oriented agencies such as EPA, FDA, CDC, and the National Science Foundation expand their roles in this area.
- o The research committee review existing programs and the proposed research agenda, determine whether it is appropriate to transfer portions of DOE's research budget to other agencies, and, if it is appropriate, recommend which projects to transfer.

In response to the last recommendation, the Interagency Radiation Research Committee (IRRC) did review the entire Federal radiation research program, but contrary to commonly held perception, did not recommend transferring any part of the Department's radiation program or budget to other agencies. However, former Department of Health, Education and Welfare (DHEW) Secretary Califano, despite the findings of the IRRC and the Task Force, recommended that "...the major responsibility for research into the health effects of low-level radiation be placed on an agency which has

health-related research as its primary responsibility." The attached letter to Senator Glenn from Dr. Gilbert Omenn, former Associate Director of the Office of Science Technology and Policy, may clarify this issue.

The fundamental question regarding transfer is: Can the studies best be performed at DOE or at some other agency or agencies? The facts clearly show that DOE is performing these studies in the best manner possible, which clearly is in the best interest of the workers and the public. Improved communication of research results to workers is a more effective step toward elimination of the perception of conflict of interest than a disruptive transfer of the programs to another agency. DOE has, during the past two years, initiated an outreach program to address the previous lack of direct communication with workers and their surrounding communities; this initiative will continue and be enlarged in the future. Particularly in light of the fact that scientific credibility is not an issue here, nor is there any actual conflict of interest, the Department is strongly against the transfer of radioepidemiologic activities to another agency.

The sole justification for incurring the negative effects associated with transfer is to avoid the <u>appearance</u> of conflict of interest to a few people. The advisory panel called for in the proposed legislation is, to a large extent, already in place in the form of the Health and Environmental Research Advisory Committee (HERAC). Because of my concern that epidemiologic research be of the highest quality and above suspicion, two years ago I asked HERAC to commission a subcommittee to examine the program in detail.

Their recommendations, as contained in their report (Appendix 1), and the Department's response to these are as follows:

o Office of Health and Environmental Research (OHER) should assume leadership role in radiation and other energy pollutant epidemiology studies

We strongly concur with this recommendation, and are acting on it, particularly with respect to developing new targeted studies, broadening the information base in existing studies, and placing the health consequences anticipated from the use of other energy sources in perspective.

o Objectives need clear formulation

In general, the objectives of the epidemiology program are to provide information on the health risks of energy generation and use to help assure the health and safety of DOE workers and the general public, and to improve the scientific data base. We currently are refining these objectives and developing criteria for assessing if studies are meeting these objectives.

o Institute management changes to improve credibility

- o Institute competitive bidding, including proposals from outside the laboratory system
- o Provide for periodic external review
- o Provide funding for university participation
- o Make databases available to outside scientists

The OHER policy is to accept unsolicited proposals for new research efforts from onsite laboratories, universities, and private organizations. Currently, the OHER peer review process includes review of proposals by experts in the field, periodic site visits during the contract period, and

submission of research results for publication in peer-refereed scientific journals. The epidemiology program, as a whole, has been the subject of a comprehensive peer review in 1983 and a review by HERAC in 1984. Specific studies at the Savannah River Plant were reviewed by the Centers for Disease Control in 1984. Each study has its own independent Advisory Committee which meets at least once a year. These reviews and committees include several experts outside of the DOE system. In addition, we have recently initiated an outreach program to involve workers in the conduct and review of ongoing studies which affect them.

Funding is now provided for the participation of university scientists and training of students in several studies including those conducted by the Oak Ridge Associated Universities (ORAU), Hanford Environmental Health Foundation/Pacific Northwest Laboratory (HEHF/PNL), Brookhaven National Laboratory (BNL), Lawrence Berkeley Laboratory (LBL), and Los Alamos National Laboratory (LANL).

Within the confines of the Privacy Act, databases are available to qualified scientists under the Freedom of Information Act.

o Devote more attention to the study of other potential toxic agents

The Health and Mortality Study components have begun to concentrate more on investigating the effects of exposure to toxic agents in the workplace as individual risk factors and through interaction with radiation. This study is probably the only one which is able to address these combined effects. Specific emphasis will be placed on identifying the agents responsible for any mortality or morbidity excesses which do not appear to be attributable to radiation exposure.

o Improve program coordination

As recognized by the committee, steps have been taken in recent years to substantially improve program coordination. These steps include the holding of contractor meetings, eliminating conflicting responsibilities among contractors, initiating mutual assistance agreements for data gathering and sharing, and investigating pooling and parallel analyses of data.

o Provide strong support for Radiation Effects Research Foundation (RERF)

We strongly concur with this recommendation and will continue our long-term support.

o Initiate studies to address gaps in our scientific knowledge

We consider the suggestions for such studies to be extremely useful, and we will be initiating new studies or modifying existing ones to provide information to fill the identified gaps in knowledge.

o Explore new approaches in genetic studies

We concur with the recommendation and are acting on it by coordinating a new research program between two OHER divisions.

In establishing the Atomic Energy Commission, the Atomic Energy Act of 1954 authorized and directed the Commission to "...make arrangements (including contracts, agreements, and loans) for the conduct of research and development activities relating to...the protection of health and the promotion of safety during research and production activities...". The Department of Energy and its predecessor agencies have a long history of scientific accomplishments and important contributions to the health and

general welfare of the American people. The same concern and dedication reflected in the Department's mission-oriented research is an integral part of our radiation epidemiology program. The Department believes that inherent in its mission to assure an adequate energy supply for the nation is the necessity to maintain research to ensure that this is done without detriment to the health and safety of the public or to its own workers.

We believe that these studies are extremely important, and would welcome another agency funding similar studies to assure the reliability of the results from DOE-sponsored radioepidemiologic research. Nevertheless, the Department would still have to continue this research in order to meet its mandated responsibility to assure the health and safety of the employees working in its facilities.

This concludes my prepared statement. I would be pleased to answer any questions you may have.

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school of public health and community medicine

office of the dean, sc-30
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8 June, 1985

Honorable John Glenn
Committee on Governmental Affairs
U.S. Senate
Washington, DC 20510

re: S.525

Dear Senator Glenn:

I have become aware, as a member of the Advisory Committee to the Hanford Mortality and Morbidity Study, that S.525, the "Radiation Reorganization Act of 1985" proposes to transfer authority to conduct epidemiologic studies of the effects of radiation from the DOE to DHHS.

It may interest you to know that we had an intensive review of just this issue a few years ago, when I was Associate Director of the OSTP under Frank Press. At that time, Joe Califano was eager to take over this function, and the notion that totally disinterested parties must be the only agencies responsible for particular kinds of research was prevalent in the Administration. Nevertheless, after review of the merits of the program in DOE and its predecessor agencies and especially after consideration of the relative priorities given to such research in the two departments, an affirmative decision was made to retain such studies in the DOE.

Continuity of registries and ongoing epidemiological surveillance is of the greatest importance; often such continuity is sacrificed when grants are awarded through the NIH peer review system for the latest and newest ideas and hottest methods. It was my impression then and remains my impression now that the DOE has carried out this research with considerable effort to assure external peer review and with the necessary commitment to continuity and to addition of new research methodologies.

I recommend that you leave this function in DOE and provide adequate oversight, either through the Government Affairs Committee or through other Committees.

[illegible] Spiral Catcher . . a Northwest Coast Indian implement used by shamans or spiritual healers to ward off spirits that brought physical or mental illness. These instruments were usually carved from the long bones of large animals and handed down from generation to generation

If you or your staff have questions of me, please do contact me.

Best wishes.

Sincerely yours,

Gilbert S. Omenn, M.D.,Ph.D.
Professor & Dean

Appendix 1

REVIEW OF THE OFFICE OF HEALTH & ENVIRONMENTAL RESEARCH PROGRAM

EPIDEMIOLOGY

Prepared by a Subcommittee of the Health & Environmental Research Advisory Committee
Office of Energy Research, Department of Energy

September 1984

REVIEW OF THE HEALTH & ENVIRONMENTAL RESEARCH PROGRAM

EPIDEMIOLOGY

Prepared by a Subcommittee of the Health & Environmental Research Advisory Committee (HERAC)

Office of Energy Research
Department of Energy

September 1984

EXECUTIVE SUMMARY

The DOE Health and Environmental Research Advisory Committee (HERAC) has reviewed the Department's epidemiology research program within the Office of Health and Environmental Research (OHER). In a letter dated March 19, 1984, Dr. Alvin W. Trivelpiece, Director of the Office of Energy Research, asked HERAC to conduct this review and advise him on the appropriateness and future directions of the program (see Appendix A). The review was conducted by a subcommittee of HERAC which included members of HERAC and other scientists selected for their expertise in areas related to the program (see Appendix B). The report was reviewed and approved by HERAC. This summary is organized according to the questions raised by Dr. Trivelpiece's charge, followed by summary recommendations.

1. Need for the DOE Epidemiology Program?

The DOE and its predecessors, ERDA and the AEC, have historically taken the lead in anticipating human health consequences from radiation and other toxic agents. The AEC/ERDA/DOE sponsored studies in radiation epidemiology have provided much of the presently available information on the human health effects of ionizing radiation, both somatic and genetic. The program has supported studies of A-bomb survivors, patients receiving radium or thorotrast for therapuetic or diagnostic purposes, radium dial painters, the Marshallese Islanders exposed to fallout from weapons test in the Pacific, radiologists, infants exposed in utero during maternal X-ray pelvimetry, uranium miners, and various other exposed groups including its own and contractor employees. The program has been of immense importance as a source of scientific information about human radiation effects. The current scope of the program includes the Japanese A-bomb study, medium-to-high dose

radiation studies (radium dial painter and New Mexico uranium miner studies), low dose studies of DOE and contractor workers ,including special studies of those exposed to uranium or plutonium, and studies of risks associated with new energy technologies (shale oil, coal gasification and coal liquefaction workers).

There are several good reasons for the DOE to support epidemiologic research related to the nuclear and fossil energy industries. The DOE has an inherent responsibility to monitor and ensure the safety of employees in these industries and of people who may live near the related facilities. The Department plays a unique, central role in managing many energy- and weapons-related programs and thereby has access to a large resource of occupational health data. The DOE's major commitment to these programs argues strongly for strengthening its leadership role in determining the human health effects from such technologies. The DOE cannot entrust this commitment to other government agencies where it may deteriorate through lack of interagency cooperation or future loss of priority. The DOE also supports a large toxicology research program that provides additional strength to its epidemiologic research. The working relationship with the DOE occupational hygiene and health physics programs is an invaluable resource that the DOE must maintain and cultivate.

Workers at the DOE facilities have had exposure to radiation and a number of other toxic agents. For the purpose of worker protection DOE therefore needs to have an epidemiological surveillance and monitoring program to assess possible adverse long-term effects from such exposures and to validate the appropriateness of the standards. Having available systematic databases on employee exposures, risk factors and health experience, with the findings from these published in the open scientific literature, is also important for documentation and equity in legislative and judicial proceedings. Thus, strictly in regard to surveillance, it is absolutely essential that the DOE support high quality epidemiologic studies of its present and past employees.

2. Scientific Merit of the Work?

There are compelling scientific reasons mandating support for the epidemiologic research. These studies address several important present day gaps in our knowledege of human radiation effects. The study by the Radiation Effects Research Foundation (RERF) of the A-bomb survivors in Japan is the preeminent radiation epidemiology study in the world. It has provided the best human information to date on a number of central radiobiological issues, with regard to both somatic and genetic effects. Also, the DOE-worker studies provide unique and important sources of information. For instance, the plutonium workers study is the only major study in this nation, and perhaps in the world, to assess the human health effects of Pu exposure, an issue of great public concern and significance for future policy with regard to the use of nuclear fuels.

Although estimates of low-dose radiation effects have been derived largely by extrapolation from high-dose studies and from our understanding of biological mechanisms, there is a need to verify directly the estimates made by extrapolation. The DOE-supported low-dose radiation studies attempt to do this. Their major scientific contribution to radiation epidemiology may be to establish narrower empirical upper limits on risk at low doses than have been available heretofore. The DOE worker studies also have the potential for scientific contribution to our knowledge of the effects of other toxic agents, alone and in combination. This is an area of pressing need for both scientific and sociopolitical reasons.

Much of the resources devoted to the DOE worker studies over the last several years have, of necessity, been used to assemble large, historical databases. As the database assembly is completed, these studies have the potential for increasing their scientific productivity and addressing many questions about the health effects of nuclear and non-nuclear technologies. The need for epidemiologic health surveillance together with the potential

for scientific contributions constitute a persuasive rationale for strong continued support of these studies.

3. Are there other energy-related human health issues which should receive higher priority?

The Committee recommends increasing attention to the epidemiologic study of potential toxic agents other than radiation, and, particularly, the investigation of the joint effects of exposure to multiple toxic agents. Several recent legislative and judicial developments have indicated a pressing need for such information. For situations involving exposures to combinations of agents, the use of exposure control standards based on single agents may or may not account for the total risk. This is an important industrial hygiene concern as well as a major stumbling block to the resolution of injury litigations. It requires the best possible quantitative data on humans. Especially with regard to radiation plus other hazardous agents, the DOE has both the need and the capability to develop such data.

Similarly, a strong case exists for the collection of more and better information on smoking and other lifestyle factors in the DOE epidemiologic studies. Current information is inadequate to determine if risks associated with radiation or other toxicants are modifiable by lifestyle factors. There is a pressing need to reduce such uncertainties in response to both scientific and sociopolitical concerns.

One of the ultimate goals of the epidemiology program is to validate our understanding of the mechanisms underlying various health effects. As knowledge about mechanisms is developed by molecular biologists, toxicologists, radiobiologists and others, it is desirable that interdisciplinary programs be instituted to apply the insights and techniques.

4. What directions should the RERF studies take in the future? Should support of this work be continued indefinitely? Are there other scientific approaches that should be employed in the RERF studies?

The RERF A-bomb studies in Japan strengthen the scientific aspects of the present OHER epidemiology program with respect to both genetic effects and disease endpoints. These studies are, without doubt, the most important and fruitful human studies concerning the effects of ionizing radiation that have ever been undertaken; their continued support by DOE is certain to prove rewarding. The RERF studies of solid tumors will become increasingly informative in years to come as more radiogenic cancers accumulate and as the younger groups at the time of exposure to the bombs reach the ages of greatest cancer risk. As the number of radiation-induced cancers is augmented year by year, it will be possible to obtain more precise estimates of the magnitude and temporal pattern of radiogenic cancer risk. RERF substudies are now ongoing or being planned which will enhance our scientific knowledge of the role of age at exposure, sex, lifestyle factors, and other environmental exposures in modifying the carcinogenic response to radiation.

With reference to genetic epidemiology, OHER has a long record of support of human studies of mutation in Hiroshima and Nagasaki. These studies, which are the only really significant source of data on the genetic effects of radiation on humans, are about to enter a new and more promising phase with implementation in Hiroshima and Nagasaki in the next several years of the newest techniques for studying proteins and DNA. At the same time, efforts are underway to preserve the cell lines from the A-bomb survivors and their offspring, so that this unique resource will not disappear but will be available for future genetic studies.

Summary Recommendations

The subcommittee has a number of recommendations to make regarding the epidemiology program. More detailed recommendations are given in the main body of the report.

- We urge strong support of the OHER epidemiology program for two reasons. (a) In this era of litigation over the health effects of exposure to ionizing radiation at low levels, the DOE cannot affort to be without a substantial and high quality database from which to study the effects of exposures incurred by its workers. Because of the various legislative and judicial proceedings in the radiation area, it behooves the DOE to have available the means to evaluate the risk associated with nuclear technologies. The same reasoning applies to the epidemiologic study of other potentially hazardous agents in the workplace and to non-nuclear energy technologies. (b) Among the studies supported by OHER are classic studies of exposures to internal emitters (radium dial painters and plutonium workers) and external radiation (RERF A-bomb study), which are providing unique and invaluable scientific data.

  It cannot be overemphasized that a program such as this requires continuity in funding. It takes a number of years to assemble such large datasets, and maintenance of good quality documentation of exposures and health endpoints requires a sustained commitment of resources.

- We recommend that certain aspects of the program be strengthened. The program would benefit from a review and clear statement of its objectives, and the rigorous use of the objectives in program evaluation and program planning. In addition, we recommend an increased emphasis on targeted, higher-dose studies which have the potential to address radiobiologic questions for which we currently have little or no human data.

Measures to improve the coordination among the several epidemiologic studies, and to increase the communication between the epidemiologic and experimental research groups in OHER, would also enhance the program. Coordinated, joint analyses of the several low-dose studies would increase their scientific value by allowing more reliable estimation of bounds on the magnitude of low-dose effects.

One of the issues facing the DOE is how to respond to litigation that is being pressed against it. The litigation almost inevitably involves questions of dosimetry, evidence that there have or have not been adverse effects, synergism between radiation and other types of exposures, credibility of the conventional estimates of risk as applied to low-dose situations, etc. It seems clear that attention should be given to ensuring that the epidemiology databases are designed and implemented in such a way as to be maximally relevant and effective in providing pertinent information in such litigation situations; as a minimum, this would mean having complete and accurate information on exposures to radiation and other toxicants, and it is hoped that, over time, information on smoking and other lifestyle factors can be assembled.

- We believe the program would improve its credibility in the scientific community and among the general public if more openness is fostered by the OHER management. Measures to accomplish this might include: open solicitations for competitive research proposals in areas of program interest, increased use of peer review mechanisms with more outside scientific experts, mechanisms to increase collaboration between the DOE epidemiologic research groups and university groups, and independent review and re-analysis of results by scientists outside the DOE program.

- The Committee endorses the new directions the RERF studies have been or will shortly be taking, namely, to increase the information on factors

which may modify the carcinogenic response to radiation, and to develop new, more sensitive techniques to study mutations. DOE support of the RERF studies is extremely important and should continue for at least the next twenty years.

° The DOE should explore the potential of new approaches in genetic studies, not only for human populations but in a mouse model. A prompt evaluation of the usefulness of these approaches with a mouse model would not only validate (or refute) the investment in a human study but permit explorations of the nuances of the approaches which are now possible for potentially mutagenized human populations. It is further recommended that in any major new round of genetic studies, in the same populations of both humans and mice, indicators of genetic damage in somatic cells be pursued simultaneously, in order to begin to build the necessary bridges between somatic cell and germ cell studies.

° We recommend that efforts be made by the epidemiologic program management to identify and address gaps in our knowledge. The subcommittee identified several such gaps, including information on: the magnitude of risk from neutron exposures; the effects of radiation dose-rate on the magnitude of risk; the joint effects of workplace exposures to multiple toxic agents; how lifestyle factors (e.g., smoking) may modify people's risk from radiation or other hazardous agents in the workplace; the role of genetic and host-susceptibility factors in modifying risk from radiation.

DETAILED REPORT

EPIDEMIOLOGY SUBCOMMITTEE MANDATE AND ACTIVITIES

In response to Dr. Alvin Trivelpiece's charge to the Health and Environmental Research Advisory Committee (see Appendix A), a Subcommittee was formed to provide an evaluation and overview of the DOE-OHER Epidemiology Program. To provide an independent and objective review, outside members were selected who had little or no involvement with the Epidemiology Program. The Subcommittee included a diversity of expertise, namely, radiation epidemiology, environmental epidemiology, toxicology, pathology, genetics and risk assessment. The affiliations of Subcommittee members appear in Appendix B.

The Subcommittee has attempted to address each of Dr. Trivelpiece's questions in this report. We did not undertake independent evaluations of individual projects but confined ourselves to an examination of the general nature of the program in relation to the field of epidemiology, and especially radiation epidemiology.

The Subcommittee benefited by information from various sources: a DOE Contractors Meeting in May 1984, where presentations were made by DOE-supported epidemiologists; a presentation by Seymour Jablon at our meeting on July 9-10 describing the research on A-bomb survivors conducted by the DOE-supported Radiation Effects Research Foundation (RERF); a report of the 1982 DOE Radiation Epidemiology Contractors' Workshop, which provided useful information on specific programs. Of particular importance as a complement to our deliberations were the reports of site visits made to the epidemiology groups at most of the DOE labs in 1982-83, an activity initiated by the OHER Epidemiology Program. These reports were an extremely valuable resource on specific programs and their accomplishments.

THE ROLE OF OHER-DOE IN EPIDEMIOLOGY: Past, Present and Future

The AEC/ERDA/DOE sponsored studies in radiation epidemiology have provided most of the information we now have on the human health effects of ionizing radiation, both somatic and genetic. Supported studies include: A-bomb survivors, patients receiving radium or thorotrast for therapuetic or diagnostic purposes, radium dial painters, the Marshallese Islanders exposed to fallout from weapons test in the Pacific, radiologists, infants exposed in utero during maternal X-ray pelvimetry, uranium miners, and various other exposed groups, as well as DOE's own employees. The importance of this program has been very great from the scientific standpoint.

Epidemiologic studies presently supported by DOE largely concern as subjects DOE and DOE-contractor employees along with the A-bomb survivors and radium dial painters. There are also several small studies of workers involved in the production of energy from sources other than those in general use. The program projected for the future appears to reflect the current, rather diffuse objectives, and could benefit from a formulation of more focused scientific objectives.

RATIONALE AND OBJECTIVES OF THE OHER-DOE EPIDEMIOLOGY PROGRAM

There are several good reasons why DOE should be conducting epidemiologic research related to nuclear and fossil energy industries. DOE bears an important responsibility for the safety of employees in these industries and of people who may live near the related facilities. The Department plays a unique, central role in managing many energy- and weapons-

related programs and thereby has access to a large resource of occupational health data. It also supports a large toxicology research program which gives additional strength to its epidemiology research.

The knowledge needed to protect workers has diverse sources, including formal studies of the workers themselves and other studies supported by DOE and its predecessor agencies. To enhance the level of knowledge, studies of workers are useful but certainly not sufficient: opportunities for studies of other populations, especially those exposed to higher than occupational levels are essential. The knowledge gained through the program of epidemiologic studies thus benefits society generally, and provides part of the underpinning for radiation protection programs of wider applicability, for risk estimation, and for understanding disease mechanisms, especially cancer and genetic effects.

Potential objectives of the DOE-OHER epidemiology program include:

Objective A:

To provide comprehensive health surveillance programs for workers in Department of Energy facilities and for populations who reside in the vicinity of these facilities.

Although many criticisms have arisen concerning the openness and objectivity of the OHER Epidemiology Program, the Department of Energy cannot ignore its inherent responsibility to monitor the health of workers and the public who may be exposed to toxic products used in its facilities. This has several ramifications. It provides a data base for establishing or modifying exposure control standards, and it establishes a basis for a legal response to court challenges of past procedures of the energy industry which involved exposures to workers or to the public.

Most of the current efforts focus on documentation of potential health

effects of ionizing radiation. However, this surveillance needs selective expansion to include exposures to chemically toxic substances and to mixtures of chemicals and radiation. The Department of Energy must continue to support these efforts in order to demonstrate its responsiveness and sensitivity to public concerns, even if there is little possibility of observing meaningful changes in the health status of the study populations. Because criticisms of the Department of Energy would very likely increase with cessation of its health surveillance programs, the responsibility for collecting and maintaining worker dosimetry and health records should continue to receive priority funding and not be allowed to transfer to other agencies where its future support might be de-emphasized at a later time.

With respect to surveillance of the health status of populations living near Department of Energy facilities, the role of the OHER Epidemiology Program is less clear. At a minimum, researchers should be prepared to respond to reports of increased health risks to the public resulting from Department of Energy programs. This need not require the development of new data bases in most cases, since health statistics for localities are becoming increasingly available.

Objective B:

To conduct epidemiologic studies to improve our scientific understanding of toxicologic processes and develop dose-response relationships.

With the documentaion of the health status of workers exposed to toxic agents, rigorous analyses should determine if they incurred added risk. This information has use in formulating exposure control standards for workers and the public, and in resolving potential injury litigation. One step in meeting this objective is the development of quantitative exposure-dose-risk relationships; the main limitation in establishing these relationships is usually the lack of quantification of exposures. In any event, analyses

should be performed to determine the upper limit of health risks that may relate to specific levels of exposure.

To fulfill objective B, potential study populations will need to undergo careful screening to determine their suitability for developing quantitative exposure-risk relationships. This should include consideration of population size, exposure magnitudes, quality of exposure information, period available for follow-up study, potential for completing a successful study and applicability of the study to important Department of Energy concerns. The Subcommittee recognizes that many potential study populations are suitable for meeting Objective A, but few are good candidates for meeting the more selective criteria related to Objective B. Detailed discussion of this appears in reports by the National Research Council (1) and Dreyer et al. (2).

Objective C:

To advance the science of epidemiology and risk assessment while focusing on studies of health effects caused by ionizing radiation, both alone and in combination with exposures to toxic chemicals.

The Department of Energy continues to occupy a leading position in the advancement of scientific knowledge on the health effects of ionizing radiation in human populations. Researchers in its epidemiology program have access to vast data bases containing radiation exposure records for thousands of nuclear industry workers and people exposed to nulcear weapons explosions. This working relationship with Department of Energy occupational hygiene programs is an invaluable resource that the DOE must maintain and cultivate, and one that it cannot entrust to other government agencies where it may deteriorate through lack of interagency cooperation or future loss of priority.

Because the current radiation epidemiology program includes studies of

worker populations located at many different types of industrial facilities throughout the United States, it is necessary to develop database linkages which will permit the coordination of research results necessary to support common findings. This approach is vital to gain an understanding of health risks caused by exposures to multiple toxic agents in workplaces, an issue of primary concern in the development of future exposure control guidelines. This approach may also entail the design of a series of methodologic studies to learn how to optimize such multi-facility research.

The Department of Energy epidemiology program has produced most of our current knowledge on the effects of low-level radiation in human populations. It has also identified important information gaps that are now being addressed through combined efforts of the OHER epidemiology and laboratory toxicology programs. Examples of this research are the development and use of short-term bioassays for human risk assessment, the evaluation of genetic risks of radiation and the projection of health risks from exposures to complex mixtures of toxic substances. Health effects from toxic chemicals may be observed in some of the worker populations, but adequate retrospective exposure information will be very difficult to obtain. However, most of the studies will at least provide some indication as to whether or not current exposure standards need modifying or if legal disputes are likely to arise in such numbers as to require broad-based legislative or judicial actions.

PROGRAM EVALUATION BY THE SUBCOMMITTEE

In evaluating the DOE worker studies, it is important to bear in mind that they have two components: (1) the protection and surveillance of workers' health; and (2) the creation of new and useful scientific knowledge. Regarding the second component, no matter how well done technically the low-dose studies are in regard to radiation effects, they have intrinsic limitations in their scientific value, because of their constraints having to

do with the low frequency and proportion of cancers (or other untoward health effects) attributable to radiation exposure. (Also see Appendix C).

The magnitude of low-dose effects, a main issue in these studies, is a practical matter of great concern. However, it seems likely that reliable estimates of low-dose effects will have to be derived (a) from the consequences of exposures at higher doses, where the magnitude of effects can be measured, and (b) with the aid of dose-response models based on the best theoretical understanding of mechanisms. The main scientific contribution of the low-dose studies is made largely insofar as they permit establishing useful upper limits on risk.

It should be noted that a blanket indictment of "low dose" studies should not be made because: (1) the studies are also helping fulfill DOE's responsibility for health surveillance; (2) having a few low-dose studies of low-LET radiation is probably important to assess and answer the claims by some parties that risks are, say, 20 or 100 times as great as generally believed; (3) the studies can also address the issues of concomitant exposures to other potentially hazardous agents; and (4) some of the studies address important gaps in our knowledge. (E.g., the plutonium workers study is the only major study in this nation, and perhaps in the world, to assess the human health effects of Pu exposure; the low-to-moderate dose, New Mexico uranium miners study may provide important information about radon exposures at levels below those of the Colorado miners study, but still at levels high enough to observe consequent risks.) Nevertheless, the present program, from the standpoint of its contribution to science, needs a better balance between the studies of low-dose effects and other studies.

The scientific aspects of the present program are given breadth by the RERF studies in Japan that address both genetic and somatic endpoints. These studies are without doubt the most important and fruitful human studies concerning the effects of ionizing radiation that have ever been undertaken, and their continued support by DOE will no doubt prove to be rewarding. In the next few years the RERF studies of solid tumors will become increasingly

informative, as the number of radiogenic cancers increases and the younger groups at the time of exposure to the bombs reach the ages of greatest cancer risk. Seventy percent of the population (all ages) was still alive in 1978. As the number of radiogenic cancers increases, it should be possible to learn much more about the role of not only age at exposure but also of sex, lifestyle factors, and other environmental risk factors in modifying the carcinogenic response to radiation. (The available number of radiogenic cancers is the limiting factor in such analyses.)

In the past, attempts were made at RERF to perform autopsies on all deceased members of the major study sample (Life Span Study Sample). The proportion of postmortem examinations among such persons decreased with time to a level where the autopsy subset was thought not to be representative of the larger group. For this and related reasons (including especially the attendant costs), the autopsy program was significantly reduced in scope in 1978. Recent events suggest that this issue should be re-examined with consideration given to the development of a highly focused autopsy program. Such a program would be structured around groups of individuals with disease entities or exposure histories that are thought to be unique and where the autopsy would be expected to add significantly to our understanding of one or more aspects of radiation injury, such as, persons exposed in utero and individuals with two or more suspected primary malignancies. As a next step, it might be appropriate to bring together a group of several pathologists with interests in radiation injury to discuss the feasibility and possible scope of such a program.

With reference to genetic epidemiology, OHER has a long record of support of studies of mutation in humans, primarily in connection with the program of RERF in Hiroshima and Nagasaki, Japan, but to a lesser extent, in the U.S. as well. Although the Japanese studies were originally morphological in nature, as new techniques became available, such as those of cytogenetics and one-dimensional electrophoresis, they have been introduced into Japan. These studies, which are the only really significant source of

data on the genetic effects of radiation on humans, have yielded a very tentative estimate of the genetic doubling dose for mutations of about 160 rem of acute radiation. Genetic studies are about to enter a new and more promising phase as the newest techniques for studying proteins and DNA are implemented in Hiroshima and Nagasaki in the next several years.

However, all of radiation epidemiology cannot be built on the experience of the A-bomb survivors, valuable though it is. The complexity of radiation exposure, and the ways in which that complexity influences risk, are such that many other experiences need to be studied, experiences that provide clues, for example, to the influence of dose-rate and dose-fractionation, of high-LET radiation of different kinds, of internal emitters, and of partial-body exposure. Important insights into the mechanisms responsible for cancer may flow from more specific quantitative information on variation in the risk of radiogenic cancer associated with host and environmental characteristics. To study these sources of variation requires large numbers of radiogenic cancers, which are just not beginning to become available among the A-bomb survivors. A program of radiation epidemiology with scientific objectives should have such breadth.

The DOE program would benefit scientifically from a better balance between the low-dose studies and those aimed at an increased understanding of the sources of variation in the risk of radiogenic cancer. This might well take a larger commitment of resources, because the current surveillance of worker groups cannot be abandoned. However, it is possible that future efficiencies in the occupational study designs may also aid to a certain extent in freeing resources for new studies. (See Appendix D).

With regard to the studies of non-nuclear energy sources, the subcommittee consensus was that great care must be taken to assure that such studies have reliable measures of exposure levels and use "hard" health endpoints which are not readily subject to bias by extraneous factors. This concern arose in particular over questions about the OHER coal gasification study.

RECOMMENDATIONS

Recommendation 1:

Consonant with DOE's mission to develop and use nuclear and other energy technologies, OHER should assume a leadership role in the epidemiologic study of somatic and genetic health effects pertaining to ionizing radiation and other energy pollutants.

Clearly, DOE has a responsibility for the safety of its employees, a component of which is a health surveillance program to monitor for adverse health effects associated with such polluntants. For chronic diseases or adverse genetic effects, such surveillance requires systematic and broadly-based epidemiologic studies. At the same time, it is important to obtain the kinds of epidemiologic data that can make major scientific contributions to our understanding of the effects of radiation and other potential toxicants. Doing so will entail developing new targeted studies and broadening the information base in existing studies. The Department of Energy, should take the lead in anticipating human health consequences from the use of other sources of energy and in placing them in perspective with the health consequence of existing sources.

Recommendation 2:

Objectives for the DOE epidemiology program need clear formulation to serve as a measuring stick for all aspects of its research.

Upon specifying the objectives, the management of the program should develop criteria as to whether the studies are meeting those objectives.

This would serve both a program-evaluation and program-planning function, as it would help identify where there are over- or under-emphases in the program.

A question can be raised as to how clearly focused the studies are in conception and design and how responsive they are to potential uses. Are the study designs, choice of variables, data collection and proposed analyses being geared toward defining upper limits on risks, toward answering questions of whether there may be undue risks, associated with certain worksites, toward being responsive to needs with regard to present and impending litigation, etc.? The Subcommittee's sense for this is that, with further thought on the part of the managers and program directors, there could be some fine tuning of the studies to make them more responsive to the stated needs and goals.

In regard to ionizing radiation, the Subcommittee felt that the present program was narrowly focused in comparison with the breadth of the field of radiation epidemiology. Thus, the program planning should include a concerted effort to identify and address, where feasible, gaps that exist with respect to important unresolved issues in radioepidemiology. For example, relatively little is being done in the program to examine systematically the effects of dose-rate, host-susceptibility factors, or the possible interactive effects of exposure to multiple toxic agents (see also recommendation # 7).

Recommendation 3:

The DOE should institute management changes to improve the credibility of its epidemiology program among scientists and the public.

Measures that DOE might undertake to improve the credibility of the program include:

a. Institute a process of competitive bidding for new studies whenever possible and include proposals from outside of the Department of Energy laboratory system.

b. Provide for external review of all epidemiologic programs on a periodic basis (at least one review every three years) and include reviewers from outside the DOE system.

c. Provide funding within each epidemiology program for participation and training of university scientists and students. (The experience of the Radiation Effects Research Foundation could serve as a model.)

d. Make selected epidemiologic databases available to qualified scientists outside of the Department of Energy when appropriate, recognizing that both risks and benefits would result from such a policy.

Recommendation 4:

The DOE should devote more attention to the epidemiologic study of other potential toxic agents in addition to radiation.

A number of recent legislative and judicial developments have indicated a need for information on the joint effects of radiation plus other exposures. With exposures to combinations of agents, exposure control standards may or may not account for the total risk. This is an important industrial hygiene concern as well as a major stumbling block to resolution of injury litigations. Selective, targeted studies are clearly necessary, but since the numbers exposed to a particular toxic agent at a given DOE facility may be relatively small, the program managers would need to foster inter-facility studies and assure that data can be obtained in a uniform manner.

Programmatic emphasis should attach to studies that will develop methods of quantifying chemical exposures to workers. Hopefully, these methods can be validated and applied to other worker situations where only limited or indirect exposure information may be available. (See Appendix E).

It is also advantageous for OHER-DOE to coordinate their epidemiology and toxicology programs, so that, when good epidemiologic data become available on a particular toxic agent, animal bioassays and/or short-term tests (mutagenesis, cell transformation, etc.) be conducted as well. A series of these coordinated results would provide a linkage by which the experimental tests can be used for prediction of human health effects in the future.

A strong case can be made for collecting more and better information on smoking and other lifestyle factors in the DOE epidemiologic studies, insofar as it is feasible. It is currently uncertain whether risks associated with radiation or other toxicants may be modified by lifestyle factors, and there is a need to reduce such uncertainties. This issue is an important concern for reasons of both science and litigation.

However, a caveat needs to be added to this recommendation. It is important that the study of multiple toxicants and lifestyle factors not be allowed to detract from the quality and diversity of the main studies of radiation. The add-on studies of non-radiation factors will therefore have to be planned in a selective fashion.

Recommendation 5:

Steps should be taken to improve program coordination.

There are several ways in which intra- or inter-program coordination could be improved.

a. Although steps have been taken in the last two to three years to improve

communication and coordination among the several groups of DOE epidemiologic investigators, further improvements could be instituted, such as having meetings of the study directors two or three times a year to discuss new findings and problems, review goals, etc.

b. It is particularly important to exert efforts to increase awareness among epidemiologists of concurrent work by toxicologists, radiobiologists, molecular biologists, etc., with the intent that (a) both groups of investigators keep abreast of important new findings and issues, and (b) they enhance their efforts to improve the extrapolation of results from experimental and animal systems to humans. This would provide verification of current scientific approaches for predicting health risks from exposure to toxic agents that are based upon laboratory animal studies or bioassays; it would supplement, but not exclude, other nonepidemiologic verifications such as comparison of effects on different species.

c. Since many of the questions of health risks in the workplace are ultimately addressed by epidemiologic studies, the epidemiology program managers and study leaders should enhance their working relationships with the occupational-safety, medical, health-physics and industrial-hygiene groups at DOE facilities to ensure that the record keeping is adequate for epidemiologic needs. The development of automated systems for collecting health and exposure information should be encouraged at DOE worksites. Systematic collection of lifestyle information such as histories of smoking, previous employment and medical exposures to radiation should also be encouraged.

d. A primary aim of the "low dose" occupational radiation studies is to provide the narrowest possible upper bounds on the estimates of health risks at low doses. In principle this goal is best served by having the

largest available sample sizes. To this end, "pooled" or parallel analyses of the several low-dose datasets should yield a narrower upper bound on the range of risk(s) associated with low-dose radiation than is possible with any individual study. The subcommittee suggests constituting a task force composed of representatives from the studies and several outside statisticians, epidemiologists and dosimetrists to plan and oversee this effort.

Recommendation 6:

Provide strong support for the RERF studies of the A-bomb effects in Japan.

The Committee strongly endorses the RERF study as being a most important and productive human radiation study, and one that provides unique information. We believe it should be strongly supported for yet another twenty or more years, since the fruitfulness of the study is increasing over time.

Recommendation 7:

Initiate targeted studies to address gaps in our scientific knowledge.

The DOE should request and review new epidemiologic research proposals aimed at filling important gaps in our current approaches to occupational hygiene and risk assessment. Important information gaps currently exist in our approach to setting occupational exposure standards and evaluating worker health risks. We do not currently have:

a. Adequate information on health risks from exposures to combinations of radiation and chemically toxic substances.

b. Sufficient information on the importance of lifestyle factors (e.g. smoking and diet) in evaluating risks to workers in energy-related industries.

c. Information on dose-effect relationships for exposures to neutrons, and information on dose-rate effects for low-LET radiations.

d. Information on how background irradiation and medical radiation exposures may alter the putative occupational radiation dose-response curves. Statistical and methodologic studies are needed. (See Appendix C.)

e. Identification of sensitive subsets of human populations that may require special consideration when setting occupational exposure guidelines.

f. Evaluation of new techniques for quantifying and monitoring genetic risks in worker populations.

Recommendation 8:

The DOE should explore vigorously the potential of new approaches in genetic studies.

Recent developments with respect to protein chemistry, DNA technology, and the computer hardware and software available for the analysis of complex biological images open new possibilities for genetic studies of radiated populations. These emerging techniques have the merit of extracting far more information from a single individual than has been possible heretofore, important in view of the relatively small size of the human populations available for study and, at both the protein and DNA levels, permitting the

use of homologous indicators in humans and mice, thus meeting some of the problems in extrapolation that have arisen in the past. Very recently, pilot studies with respect to the potential usefulness of the group of protein markers visualized with 2-dimensional polyacrylamide gel electrophoresis of blood samples have been introduced into the RERF program of genetic studies, and the need to proceed to the DNA level as rapidly as possible has been recognized.

New approaches in genetic studies should be explored not only in human populations but in a mouse model. A prompt evaluation of the usefulness of these approaches with a mouse model would not only validate (or refute) the investment in a human study but permit explorations of the nuances of the approaches which are not possible for potentially mutagenized human populations. It is further recommended that in any major new round of genetic studies, in the same populations of both humans and mice, indicators of genetic damage in somatic cells be pursued simultaneously, in order to begin to build the necessary bridges between somatic cell and germ cell studies.

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Appendix A

Excerpt from a Letter by Dr. Alvin Trivelpiece, Director of the Office of Energy Research, to the Health and Environmental Research Advisory Committee (HERAC), Requesting a Review of the OHER Epidemiology Program

"OHER supports a number of studies in the area of epidemiology, including a long-term study of atomic bomb survivors in Japan which is carried out through the Radiation Effects Research Foundation (RERF). Although the individual projects have been peer-reviewed recently, there has been considerable ongoing discussion and attention devoted to some of the studies. Questions have been raised about the scientific value of some studies, and whether some were appropriate for DOE. Would you please assess the OHER epidemiology program and advise me on the need for and scientific merit of this work? Should these studies continue to be supported by DOE? Are there other energy-related human health issues which should receive higher priority? What directions should the RERF studies take in the future? Should support of this work be continued indefinitely? Are there other scientific approaches that should be employed in the RERF studies?"

APPENDIX B

DOE Health and Environmental Research Advisory Committee

Ad-hoc Subcommittee for Review
of DOE Epidemiology Program

Dr. Roy E. Shore, Subcommittee Chairman
Associate Professor
Department of Environmental Medicine
New York University Medical Center

Dr. Robert E. Anderson
Professor and Chairman
Department of Pathology
University of New Mexico
School of Medicine

Dr. Gilbert W. Beebe
Expert Scientist
Clinical Epidemiology Branch
National Cancer Institute-NIH

Dr. Patricia A. Buffler
Associate Dean for Research and
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School of Public Health
University of Texas

Dr. Theodore Colton
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Dr. Richard G. Cuddihy
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Dr. Robert Miller, Chief
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Dr. James V. Neel
Lee R. Dice University Professor
of Human Genetics
University of Michigan
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Dr. Richard Wilson, Professor
Department of Physics
Harvard University

Appendix C

BACKGROUND AND MEDICAL RADIATION EXPOSURE

Historically, studies of high-level exposures to ionizing radiation have not paid very much attention to factoring in background radiation and medical/dental diagnostic radiation exposures, because these were on average very small in comparison to the levels of exposures being studied. However, in the low-dose studies being conducted by DOE investigators, this is no longer true. The background and medical exposures may often equal or exceed the cumulative occupational exposure levels.

While recognizing that obtaining historical medical exposure information is much too costly and difficult to do on anything like a routine basis, it nevertheless behooves the program to mount some studies to evaluate the possible biasing or masking effects attributable to these other sources of exposure.

A start has already been made by the Hanford investigators (E. Gilbert) in modelling the possible effects of variations in background and medical exposures on a theoretical basis. However, it would seem appropriate for one or more special substudies to be done, wherein actual medical/background exposure data are gathered for an empirical evaluation of the potential biasing/masking effects of such exposures. This would provide a more realistic estimate of the magnitude of the variance of such exposures relative to occupational exposure levels, information on the shape of the distributions of such exposures for more realistic modeling, and a direct assessment of their potential for producing perturbations in low-dose studies.

Appendix D
EFFICIENT STUDY DESIGN

Although questions of long-term employee health surveillance suggest that total worker populations should be followed up in the studies at the DOE facilities, it would seem worth considering whether some efficiencies in study design could be implemented. In terms of the scientific yield of the studies, they are generally designed suboptimally, i.e., the vast bulk of the subjects have trivial or no radiation exposures, and a relatively small percent of the subjects contribute most of the collective person-rem in the study. (As one typical example, in the plutonium workers study, 1,025 workers who have ≥ 4 nCi depositions contribute half the total dose commitment of Pu among the 125,000 subjects in the study.) Little is to be gained in terms of statistical power by having the very large numbers of subjects at very low doses rather than a pared-down sample size there.

This subject merits some thought and discussion by the DOE management. Perhaps a two-tiered system of follow-up could be developed: a routine, less-costly level of follow-up of all workers for the purpose of health surveillance, and compilation of more detailed information only on strategic subsamples.

Appendix E

CONSIDERATIONS IN THE EPIDEMIOLOGIC ASSESSMENT OF CHEMICAL TOXICITIES

It is often suggested that exposure levels of workers can be categorized by composite indices based upon job classification, the amounts of chemicals used in a facility, and a general description of the procedures used by individual workers. However, this approach has not been rigorously validated. Valuable information could be obtained from many of the current studies involving uranium, plutonium, and other non-radioactive metals wherein bioassay information and job category information are both available. If general methods for developing exposure indices could be validated from these studies, they might well be applied to other important epidemiological studies where no exposure information currently exists. This would markedly enhance the value of many studies and should be given priority because none of the current epidemiology studies appear to adequately account for exposures to more than one type of toxic agent.

Although it is desirable to determine in the human studies whether there are interactions (synergistic or antagonistic) between radiation and other agents, it is not clear whether it will be feasible to do so in the context of the low-dose DOE studies. I.e., if one cannot see a radiation effect to begin with because of the low doses, could one expect to see, say, synergisms. Or conversely, if one does not find any interactions, how strong would such negative evidence be, given that the radiation effect is nearly undetectable?

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DOE NOTICE

This report has been prepared as a part of the activities of the Department of Energy's Health and Environmental Research Advisory Committee, a public advisory group providing extramural scientific advice to the Secretary and other officials of the Department. The document has been published by Lawrence Livermore National Laboratory, Livermore, California for the Committee. The contents do not necessarily represent the views and policies of the Department of Energy or of the Laboratory.

Statement of Robert Goldsmith, Ph.D.

Epidemiology Program Manager

Office of Energy Research

before the

Subcommittee on Energy, Nuclear

Proliferation and Government Processes

of the

Committee on

Governmental Affairs

United States Senate

June 17, 1986

Mr. Chairman and Members of the Subcommittee:

My name is Robert Goldsmith. I am the Epidemiology Program Manager in the Office of Energy Research of the Department of Energy. My undergraduate degree is in Biological Sciences from Union College. I have a Master of Science degree in Public Health/Epidemiology from the University of Massachusetts, and a Doctoral degree (Ph.D) in epidemiology from Columbia University. I have been actively engaged in the field of epidemiology for the past twelve years, during which time my research interests comprised mental retardation, smoking, diet and nutrition, and epidemiologic studies of sulfuric acid workers and nuclear power plant workers. For the past five years, I have been responsible for the administration, technical direction, and overall management of the Department's epidemiologic research program.

Suspicions that results indicating significant health risks have been suppressed by the Department of Energy can be allayed by examining the voluminous literature which has resulted from the DOE-supported studies. These papers are submitted by the authors directly to peer-reviewed scientific journals. There is absolutely no censorship or requirement for DOE review or approval. A comprehensive bibliography of publications and presentations resulting from such epidemiologic studies of DOE workers may be found in Appendix I.

Frankly, however, I believe that we at DOE have not been aggressive enough in the past in providing information on the results of our studies directly to the workers in DOE-owned facilities in a non-technical form that can be easily understood. As is usual with scientists, our contractor researchers have focused on the timely presentation of their results at scientific meetings, and the publication of these results in peer-reviewed scientific journals.

In an effort to address this problem of not directly communicating with our workers, we have set up a pilot program to determine procedures which will inform them about our studies. As a first step in this pilot program, we have instituted an outreach program in Oak Ridge to field-test various options for improving communication with workers at all DOE facilities. In this program we will be communicating with the workers and the general public. This pilot program includes the following components:

- Presentation of research results by ORAU epidemiology staff in regularly scheduled labor/management health and safety meetings.
- Preparation of summary reports in layman's terms of scientific journal articles for distribution to interested employees.
- Copies of published papers sent directly to management, labor, and/or other employee representatives at the plant(s) involved. Copies also sent to plant(s) libraries, information center, or other convenient locations where they will be accessible to all employees.
- Periodic updates on progress and results of studies published in company newsletters.
- News releases about studies' results for distribution to local media.
- Establishment of telephone number "hot line" which workers can use to ask ORAU investigators any questions they may have regarding epidemiologic studies.
- Open door policy at ORAU's Center for Epidemiologic Research including tours, seminars, etc. at the workers' request and convenience.

- o Solicitation of suggestions from workers for new studies, and their involvement in performing such studies, (e.g. chemical operators, as suggested by the Chief Steward of the International Chemical Workers Union Local 715).
- o Periodic visits by DOE Headquarters staff for direct meetings with workers.

In addition, we have established a Safety Coordination Committee, chaired by the Deputy Director of the Oak Ridge Operations Office, and including myself and representatives of each labor union in Oak Ridge, which meets quarterly to discuss health and safety concerns and provide a focal point for dissemination of information on the progress and results of epidemiologic studies of workers at the Oak Ridge facilities.

Also, we are advising all Operations Offices of our commitment to keeping workers informed, and are establishing uniform specific procedures and timetables for such information dissemination. We realize that credibility comes from understanding, and understanding comes from communication. As part of this evolutionary process, we now have begun to communicate better; we have started, and we will continue.

I would like to address the administrative approach we take to ensure the technical competence of each and every epidemiologic study which we support. Each study has its own independent oversight committee, composed of renowned epidemiologists, physicians, and other scientists. There is absolutely no evidence that the methods used by DOE contractor scientists are incorrect or not the best possible. For example, one cannot assert that the Department seeks to minimize risks by using comparisons with the U.S.

general population (i.e., Standardized Mortality Ratios), when in fact, this is generally accepted as standard practice. This type of comparison is used to generate hypotheses which subsequently are tested by comparing exposed workers with unexposed workers in the same facility, or by subsequent case-control studies. The comparisons are technically sound and are used routinely by occupational epidemiologists nationwide, including those at the National Institute for Occupational Safety and Health.

In general, our epidemiologic studies have both a scientific and a practical purpose. The scientific purpose is to provide the best information on health effects related to energy generation and use. The use of this information for standards setting, remedial actions, checking of compliance, etc. is completely separate from and is not a responsibility of the Office of Energy Research. We do, however, inform the appropriate Operations Offices of the results of these studies, and transfer to them the formal report of the study and any literature to be disseminated to the workers. The practical purpose of the epidemiologic studies is to obtain information on the health and safety experience of present and former DOE and DOE-contractor workers, and to identify the causes of possible deleterious health effects.

In my opinion, the peer review process which covers these studies ensures that the best scientific work is being accomplished without any potential conflict of interest. This process involves proposal review by scientists outside DOE prior to initiating a new study, independent advisory panels for each study, periodic peer-review site visits, oversight by the Department's Health and Environmental Research Advisory Committee, and sub-

mission of all research papers for publication in peer-reviewed scientific journals. This is, of course, standard operating procedure at DOE in all areas of scientific research.

The difficulties and negative effects of the proposed transfer of authority in the legislation, S. 525 are numerous. Substantial expenditures of time and effort, as well as significant delay, would surely be expected. Much data, such as hard-copy death certificates, personal security questionnaires, and personal identifiers, cannot be transferred. That is, agreements with States and some Federal agencies (e.g., the National Center for Health Statistics for use of the National Death Index) would require renegotiation by any party taking over such research. Existing contracts with DOE-supported scientists would have to be terminated, and selection of new contractors certainly would take much time. It is not a simple problem to transfer databases. An effort requiring software development and possibly some hardware modification would be required. Indeed, the mechanics of transfer, alone, are formidable. Furthermore, the likely fragmentation of the program among several agencies will result in duplicative loss of efficiency (e.g. in death certificate retrieval) and difficulty in coordination and effective use of resources.

The Department has the legal, moral and ethical responsibility as the employer of record to assure the health and safety of its own employees. Conducting radiation epidemiologic studies is a necessary activity for

meeting this responsibility, and, whatever happens to this legislation, the Department must continue to conduct these studies.

This concludes my prepared statement. I would be pleased to answer any questions you may have.

HEALTH AND MORTALITY STUDY BIBLIOGRAPHY

APPENDIX 1

HANFORD

HEALTH AND MORTALITY STUDY

BY

BATTELLE, PACIFIC NORTHWEST LABORATORIES

AND

HANFORD ENVIRONMENTAL HEALTH FOUNDATION

Richland, Washington
December 1, 1985

Outline:

A. Database Management

1. Publications

B. Statistical Health Effects

1. Publications

2. Presentations

DATABASE MANAGEMENT

Publications

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DATE: June 17, 1986

Statement of:
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Before the:
SUBCOMMITTEE ON ENERGY, NUCLEAR PROLIFERATION
AND GOVERNMENT PROCESSES
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

Testimony Concerning the Senate Bill:
S. 525, RADIATION REORGANIZATION ACT OF 1985

Mr. Chairman and Members of the Senate Subcommittee,

My name is Roy E. Shore. I am an Associate Professor of Environmental Medicine at New York University Medical School. As to my background, I have doctoral degrees from Syracuse University in psychology and from Columbia University in epidemiology, and I am a Fellow of the American College of Epidemiology. My professional career in epidemiology has been from 1971 to the present, with research on the health effects of radiation as a prime focus throughout that time. I have served as a member or consultant for committees of the National Academy of Sciences-National Research Council on the health effects of radiation. I am a member of the National Council on Radiation Protection and Measurements and have served on several of their committees, including one on occupational radiation exposures. I am on the National Institutes of Health committee investigating the health risks of radioactive iodine in fallout. I am also a member of the Board of Scientific Counselors to the Division of Cancer Etiology of the National Cancer Institute.

I was asked to appear today as an independent, outside party to give my perceptions of the Department of Energy (DOE) epidemiology program. At the outset I want to emphasize I have never had a research grant or contract from the DOE or its predecessor agencies (ERDA and AEC), so I have no vested interest in the program.

I have had appreciable contact with the DOE epidemiology program, however, beginning back in 1976 when I was first asked to serve on an advisory committee to the plutonium workers study at Los Alamos National Laboratory. Since then I have been asked to serve on the advisory committees to several other DOE epidemiology projects: the radiation workers study at Hanford National Laboratory, the Naval shipyard nuclear workers study at Johns Hopkins University, and the radiation worker studies at Oak Ridge Associated Universities. I am presently chairman of the Hanford and Oak Ridge epidemiology advisory committees. I have also served on the Health and Environmental Research Advisory Committee (HERAC) which provides scientific advice to the Office of Health and Environmental Research, within which the epidemiology program resides at DOE. In 1984 I served as chairman of a subcommittee of HERAC to evaluate and make recommendations regarding the DOE epidemiology program.

One important point is that the DOE epidemiology studies have had repeated review by outside groups of peers, probably with greater frequency than many other epidemiologic studies. The advisory committees to the four studies mentioned above meet approximately yearly. In addition, these projects had the overall review by the HERAC Committee in 1984 alluded to above, plus a detailed review by an independent outside panel convened by DOE about a year before that.

The members of the various review committees have included internationally recognized experts in cancer epidemiology and radiation epidemiology, biostatistics, genetics, radiation biology, radiation dosimetry and industrial hygiene. I think it is fair to say that the DOE epidemiology studies have been monitored by a broad range of scientists of high repute and have received, as it were, passing grades.

The DOE-study advisory committees I have had a part in have performed several functions. We have closely scrutinized their methodologies--since a study can only be as good as its methodology--and where necessary have made recommendations for improvements in particular points of methodology. We have ex-

amined their preliminary results and made suggestions for further follow-up of leads of possible interest. We have discussed with them the directions in which the studies were headed and provided evaluation and suggestions concerning their plans. The study investigators have welcomed the suggestions and have usually incorporated them.

On several occasions I have reviewed drafts of manuscripts being prepared for publication by the DOE epidemiologic investigators and have made suggestions, for example, of additional informative analyses. They have been open to these suggestions, which is one indication that their intent is to analyze the results in optimal ways and not to provide a "coverup" of risks.

The soundness of the DOE studies is attested to by the good epidemiologic practices the investigators have followed. To mention a few, the investigators have maintained good quality control of the data acquisition by double coding subsamples of worker records, by cross-checking radiation exposure measurements from multiple source documents when possible, by investing sufficient resources to obtain high follow-up rates and high death-certificate ascertainment rates, and by having trained nosologists code causes of death to assure uniformity and correctness of that procedure. Their analyses have been performed in conjunction with well-trained statisticians, some of whom are outstanding in their field.

Another evidence of good epidemiologic practice, which also demonstrates their intent to pin down the nature and extent of possible radiation health effects, is their conduct of "case-control" studies (a) for the types of cancer which are thought to be the main target organs of particular types of radiation exposure (e.g., lung cancer for inhaled radionuclides), and (b) for cancer sites for which the overall analyses suggested there might be an excess risk. Case-control studies are a cost effective way to examine in detail possible associations between some disease and radiation or other occupational exposures, while effecting more control for potential biasing factors than can be done in a large, overall follow-up study.

The greatest weakness of the radiation studies in question is probably the inadequacy of the available radiation dose measurements. This deficiency comes about in several ways: radiation measurements for individual workers were sometimes sketchy or nonexistent in the 1940s and '50s; workers may have received additional occupational radiation doses when working

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at other places subsequent to their work at DOE facilities (and there is no feasible way to acquire that exposure information since the U.S. has not implemented a national radiation dose registry); and workers receive a great variety of diagnostic and therapeutic medical radiation exposures during their lifetimes. However, the important point is that these weaknesses are intrinsic limitations in the available data and are in no way the fault of the DOE epidemiology program or its investigators. It is impossible to manufacture doses for workers where measurements never existed, and reconstructing the medical exposures of the half-million or so workers in the DOE study populations would be astronomical in cost and impossible to implement. Thus, if the epidemiology program were handed over to another agency, the studies would still have the same inherent limitations.

In short, it is doubtful that the studies could be conducted appreciably better by another organization. A transfer of them to another agency would probably mean a delay in completing the studies and would increase their cost, since a new group of investigators would have to spend considerable time learning all the intricacies of the data collection and other phases of the studies. It is also unlikely that another agency would have available the same degree of expertise for the radiation dosimetry component of the studies that the DOE has; this might slow the studies down further and/or exacerbate the already existing limitations in the dosimetry.

The DOE epidemiology program contains scientists of high caliber. As you may know, there is a tendency among scientists, epidemiologists included, to want to be "where the action is"--exploring the latest new discovery or topic in their scientific disciplines. It is therefore no small feat to get good scientists to devote a number of years to large, plodding data collection efforts, such as the radiation worker studies, with the prospect that they may have few positive results at the end. I think it is a tribute to the DOE epidemiology program that under such circumstances they have been able to attract and keep a coterie of scientists of good to excellent quality.

That the DOE has continued to perform such long-term, costly studies indicates they have a concern for the health of their workers and a commitment to monitor it. I think it is doubtful that another agency of the government would have such a sustained commitment to the DOE workers. There is a real danger that another agency might pursue the studies with zest for two or three years, but then let the program languish if the investigators did not continue to find new and interesting things. I believe the long-term commitment of DOE to the epidemiology program is a compelling argument for keeping it in DOE.

Statement of Ethel Gilbert, Ph.D.
Technical Leader
Statistical Information Sciences Section
Battelle, Pacific Northwest Laboratory
Richland, Washington
before the
Subcommittee on Energy
Nuclear Proliferation and Government Processes
Committee on Governmental Affairs U.S. Senate

June 17, 1986

Mr. Chairman and members of the Subcommittee:

As a scientist who is currently involved in a Department of Energy sponsored epidemiology study, I appreciate the opportunity to appear before you today as you consider S.525, the Radiation Reorganization Act of 1985. I shall describe the scientific environment in which I work, and show that it is one that rewards competence and objectivity, and strongly discourages anything but a high level of integrity. To a large extent, I believe that the views that I will be expressing are shared by other scientists with responsibilities for epidemiological studies currently funded by the Department of Energy.

My scientific discipline is biostatistics, and I have a Ph.D. in this field. For the past ten years, I have been responsible for the analysis of data on workers at the Hanford nuclear facility. I am not employed by the Department of Energy, but by Battelle, a private research company which performs contract research for several organizations, including a major contract from the Department of Energy to operate Pacific Northwest Laboratory.

My interactions with managers from the Office of Health and Environmental Research (OHER) at the Department of Energy are infrequent. No one at OHER reviews our findings prior to submission to professional journals for publication or prior to oral presentation at professional or other meetings. There has never been any attempt by OHER to influence in any way the results that are reported.

With regard to my interactions with managers at Battelle, there has never been the slightest hint or suggestion that anything other than good scientific judgment should play a role in determining the methods that are used to analyze the Hanford data or the manner in which findings are reported. The concern of Battelle management, as I perceive it, is that the analysis of the Hanford worker study be conducted competently and in a manner that can be defended to the larger scientific community.

Our study is subject to a very strong review process. First, several papers describing both the results of analyses of the Hanford data and the statistical methods used to obtain them have been published in respected professional journals. These papers were thus subjected to review by referees appointed by the journals before being accepted for publication. Second, we have a permanent Advisory Committee which has met five times since 1980 to

review our project. In addition, our study has been reviewed by the National Academy of Sciences Committee on DOE Research on Health Effects of Ionizing Radiation (1979), and by a committee appointed by DOE to conduct an Epidemiologic Research Program Site Review (1983). The members of these review committees have included prominent experts in the fields of statistics, epidemiology, and health physics who come from universities, the National Academy of Sciences, and the National Cancer Institute. The results of these reviews have been favorable; none have found fault with either our objectivity or the adequacy of the methods we have used to analyze the data.

I regard it as very important to have my work evaluated by other scientists and to exchange ideas with others who may have different perspectives, or who may be aware of new developments in relevant scientific disciplines. I receive input not only from statisticians, epidemiologists and others at Hanford, but also from many other scientists from universities and government agencies. I attend scientific professional meetings in the fields of statistics and epidemiology, some of which have focused on the specific problems in studying health effects due to radiation. I have made numerous presentations at such meetings, many at the invitation of those organizing the meetings. (Seven such presentations were made in the last two years.) In addition, I have made several presentations to lay audiences. Thus, I am regularly exposed to many different points of view and am regularly called upon to defend our findings on a scientific basis, as well as in terms that nonscientists can understand.

It is very important to maintain continuity of studies such as the Hanford worker study. Such studies not only require management of very large amounts of data but also pose difficult statistical problems. The capabilities for conducting such studies cannot be developed in a short period of time. In the years that I have been working on the Hanford study, my colleagues and I have devoted considerable effort to developing and implementing statistical procedures that provide for an assessment of risks that are as sensitive and free from bias as possible. An early publication describing our basic methodology received an award by the American Statistical Association for the best publication in biometry in 1979. Other publications on methodology include a paper comparing the sensitivity of several statistical procedures for detecting adverse health effects due to radiation (Biometrics, 1983), a paper examining potential biases in occupational studies (American Journal of Epidemiology, 1982), and a paper describing the computer program we have developed and documented (Journal of Occupational Medicine, 1984).

In conclusion, I'd like to note that, as a scientist, it is important to me to have my work published in the best journals and to win the respect of the larger scientific community. For that reason, I have a very strong incentive to produce work that is both objective and competent, and absolutely no incentive to do otherwise. I feel a clear responsibility to make every effort to see that the Hanford worker data are analyzed using the most sensitive and unbiased methods available, and to see that the findings are interpreted and reported in an appropriate manner. I believe that this sense of responsibility is shared by other researchers working on epidemiological studies funded by the Department of Energy.

Thank you for considering my point of view. I would be glad to respond to any questions you may have.

Testimony of William J. Nicholson and Philip J. Landrigan
Before the Subcommittee on Energy, Nuclear Proliferation
and Government Processes Committee on Government Affairs
United States Senate - June 17, 1986

Mr. Chairman:

Thank you very much for the opportunity to speak before you on S.525, the Radiation Reorganization Act of 1985. My name is William J. Nicholson. I am Associate Director of the Division of Occupational and Environmental Medicine and Professor of Community Medicine at Mount Sinai School of Medicine where I have conducted epidemiological research since 1969. This testimony is jointly offered by myself and Dr. Philip J. Landrigan, the Director of the Division of Occupation and Environmental Medicine. Prior to assuming his position as Director, Dr. Landrigan was Director of Field Studies at the National Institute of Occupational Safety and Health. Dr. Landrigan is currently abroad and is unfortunately unable to appear before you. This statement is submitted by us as individuals and not on behalf of any institution.

These hearings on the proposal to transfer the principal responsibility for the conduct of epidemiological studies of the effects of radiation from the Department of Energy to the Department of Health and Human Services come at an especially appropriate time. Firstly, while much information has been developed on the health effects from radiation, much more epidemiological data are necessary to evaluate fully the emerging radiation exposure circumstances in the United States. Secondly, the large number of individuals at work in the nuclear industry requires that the potential health effects to workers in the industry, both from radiation and from other toxic agents, be more fully evaluated and understood so that proper precautions can be taken or maintained. Thirdly, the recent Chernobyl accident points to the potential for severe accidents in the nuclear industry and the need for rapid, accurate and objective epidemiological evaluations of the consequences of such. We believe that the above needs involving epidemiological studies of the effects of radiation and other toxic agents on workers and the general population can be served best by an expanded program of research under the aegis

of the Department of Health and Human Services rather than continued in the Department of Energy. Let us address the three issues mentioned above in turn.

Radiation has been one of the best studied of carcinogenic and genotoxic agents in the environment. Nevertheless, our understanding of its effects is still incomplete. Disagreements exist as to the appropriate models for characterizing the health effects from particular radiation exposures and for estimating cancer risks from exposures in the general environment. Even exposures to substantial quantities of radiation lead to disagreement among respected scientists. Estimates of the doubling doses for cancers at different sites range over an order of magnitude. The need for more radiation related epidemiological research is acknowledged by Allen Brodsky, a senior health physicist with the Nuclear Regulatory Commission who recently stated, "further improvements are needed in government support, as well as follow-up studies of both workers and members of the public exposed to radiation" (1). He would address the perceived limitations in current epidemiological research by establishing two health research divisions within the NRC, an unsatisfactory solution considering that it is an organization dominated by nuclear engineers with little expertise in health matters.

We believe that an expanded radiation effects research program under the aegis of HHS would substantially improve the quantity and quality of our epidemiological data base on radiation effects. Epidemiological research conducted under the auspices of HHS has the advantage of being able to utilize their grant program to stimulate research proposals by academic investigators that would undergo the critical peer review system of the Division of Research Grants. Further, greater access to populations employed in the nuclear industry by academic and NIH scientists would obviously increase the potential for obtaining more definitive radiation health effects data. Finally, the results of such investigations by scientists outside the nuclear industry will be more easily accepted by all individuals concerned with radiation health effects. I am not suggesting that DOE scientists are not objective. I am saying that the health effects of radiation can be an emotional issue to many affected people and it is important that radiation research

be perceived to be as objective as possible. This perception is much easier achieved with HHS supported research than with DOE research.

An essential element of use of hazardous materials in an industry is a superior health and safety program for the workers therein employed. There must be adequate medical facilities, surveillance programs appropriate to the work and exposure circumstances and, when warranted, epidemiological studies of populations or exposures of concern. Each of these programs must operate independent of the production needs of any work facility. It is clear that the maintenance of health facilities and plant monitoring must be conducted by plant personnel. However, it is important that medical monitoring programs be reviewed by an independent outside agency which also can undertake epidemiological studies of worker populations to establish the presence or absence of health effects. This is just an elementary "check and balance" that should be present whenever lives are at stake. It is no more than exists in the private sector. The role of an outside agency for such evaluations cannot be overemphasized. Again, to be effective, any epidemiological study of health conditions must not only be objective, but it must be perceived as objective.

In the case of epidemiological studies by DOE workers and reviews of existing monitoring programs this can best be done by an agency of HHS such as NIOSH, either at the request of workers or for research purposes. In principle such surveys by NIOSH can be done with the concurrence of the DOE. However, in the past the DOE has been less than cooperative in such studies. In February 1983 NIOSH received a request from the International Association of Machinists and Aerospace Workers to conduct a health hazard evaluation at the Feed Materials Production Center in Fernald, Ohio. This is a facility formerly operated by NLO, Inc. under contract to the Department of Energy. Six months of negotiations were required by NIOSH before an initial visit and tour of the facilities were allowed in October of 1983. At that time NIOSH requested health and safety reports and access to the medical and environmental records of the plants. NIOSH was informed that availability of personal records would be delayed because of the requirements of the Privacy Act. However, it was not until November 1984 that DOE proposed to give NIOSH such

medical records; access was finally granted in March of 1985. This allowed a study of approximately 150 workers to be undertaken in September of 1985, two and one-half years after the initial request for an investigation.

Delays were also encountered in a similar request for an evaluation of occupational exposures by the Oil, Chemical and Atomic Workers Union at the Goodyear Atomic Corporation, Piketon, Ohio in 1979. Here, concern was expressed by workers about exposures to radiation from urinayl fluoride. Access to the facility was delayed by DOE's initial indication that they wished to conduct the evaluation, and subsequently by delays in obtaining security clearances for NIOSH staff members. Finally, in March 1982 a three phase industrial hygine survey was begun, along with an epidemiologic retrospective cohort mortality study. Without focusing specifically on the exact reasons for the lengthy delays in each of these two investigations, their occurrence affected the credibililty of DOE in the eyes of the workers. If authority for the conduct of epidemiological studies resided within HHS, they would not have occurred and resolution of the issues would have been achieved more readily.

Finally, if a substantial accident occurs within a nuclear facility, either private or under DOE control, the need for a completely independent evaluation of the resulting hazard is especially important. At the time of any crisis initial reactions of those involved are defensive and an unbiased evaluation from members of the agency within which the accident occurred may not be immediately forthcoming. In such circumstances outside evaluation by individuals having no responsibility to the agency within which the accident occurred is clearly beneficial. In the case of DOE facilities, this can best be achieved by qualified investigators from within HHS.

The bill specifies that the HHS authority be vested in the Centers for Disease Control. We suggest that the authority to conduct epidemiological studies of radiation effects among workers be specifically vested in NIOSH. This will necessarily lead to a substantial increase in the professional and support staff of NIOSH. Clearly, provisions must be made to have this accomplished in an orderly way.

In conclusion, we believe the transfer of authority to conduct epidemiological studies to HHS has clear advantages. It will increase the number of research scientists active in the study of radiation health effects and thus, improve the quality of information. Secondly, it will provide a more accepted and efficient mechanism for investigation of health hazards to nuclear workers and others exposed to radiation.

[1]Allen Brodsky. Protecting the Public. Nuclear Power: Both Sides. M. Kaku and J. Trainer, eds. W.W. Norton, NY.N.Y. 1982.

STATEMENT OF THE HONORABLE TIMOTHY E. WIRTH
The Subcommittee on Energy, Nuclear Proliferation and Government Processes

S. 525, THE RADIATION REORGANIZATION ACT OF 1985
June 17, 1986

MR. CHAIRMAN, I WOULD FIRST LIKE TO THANK YOU FOR HOLDING THIS HEARING ON THE RADIATION REORGANIZATION ACT OF 1985, SPONSORED BY SENATOR GLENN. AS YOU MAY KNOW, I HAVE INTRODUCED THE COMPANION BILL, H.R. 1287, THE RADIATION RESEARCH REORGANIZATION ACT, IN THE HOUSE OF REPRESENTATIVES AND I APPRECIATE THE OPPORTUNITY TO PRESENT TESTIMONY ON THIS IMPORTANT ISSUE.

EVERYDAY THERE ARE TENS OF THOUSANDS OF EMPLOYEES ACROSS THE NATION WHO REPORT TO WORK IN ONE OF OUR COUNTRY'S NUCLEAR WEAPONS PRODUCTION FACILITIES. THESE INDIVIDUALS ARE A VITAL LINK IN THE CHAIN OF OUR NATIONAL SECURITY, AND YET THEY WORK UNDER A HEAVY CLOUD OF UNCERTAINTY. THEIR JOBS REQUIRE THEM TO WORK WITH SOME OF THE MOST DANGEROUS SUBSTANCES KNOWN TO MAN -- PLUTONIUM, RADIUM, URANIUM AND OTHERS. WHILE EXTENSIVE PRECAUTIONS ARE TAKEN TO ENSURE THEIR SAFETY, THERE ARE STILL MANY UNANSWERED QUESTIONS AS TO JUST HOW THESE SUBSTANCES AFFECT THE HEALTH OF THESE PUBLIC SERVANTS.

IT IS OUR RESPONSIBILITY TO ENSURE THAT WE VIGOROUSLY SEEK THE ANSWERS TO THESE QUESTIONS. YET, MR. CHAIRMAN, I FEAR THAT WE ARE NOT MEETING THIS RESPONSIBILITY IN THE MOST EFFECTIVE MANNER POSSIBLE. THE AGENCY IN CHARGE OF SEEKING THESE ANSWERS IS THE VERY SAME AGENCY WHICH EMPLOYS THESE WORKERS AND IS RESPONSIBLE FOR MEETING PRODUCTION AND BUDGETARY GOALS. THIS IS A CLASSIC CONFLICT OF INTEREST IN WHICH THE FOX IS RESPONSIBLE FOR GUARDING THE CHICKEN COOP, AND IT IS OUR JOB TO CORRECT THIS SITUATION.

OUR LEGISLATION IS DESIGNED TO ACCOMPLISH THIS BY TRANSFERRING THE AUTHORITY FOR CONDUCTING EPIDEMIOLOGICAL RESEARCH INTO THE HEALTH EFFECTS OF RADIATION EXPOSURE FROM THE FOX -- THE DEPARTMENT OF ENERGY -- TO AN IMPARTIAL AND OBJECTIVE AGENCY -- THE DEPARTMENT OF HEALTH AND HUMAN SERVICES. THE SUBCOMMITTEE HAS HEARD THE TESTIMONY OF THE EXPERT WITNESSES AND I BELIEVE THE VITAL NEED FOR THIS TRANSFER OF AUTHORITY HAS BECOME CLEAR.

THIS LEGISLATION, WHICH I FIRST INTRODUCED IN THE 98TH CONGRESS, ADDRESSES A VERY COMPLEX OCCUPATIONAL HEALTH CONCERN. THE RISKS ASSOCIATED WITH EXPOSURE TO RADIATION ARE OF MAJOR CONCERN TO THE MORE THAN 80,000 EMPLOYEES WHO WORK AT DOE-OPERATED NUCLEAR PRODUCTION FACILITIES. THESE EMPLOYEES ARE OFTEN ASSIGNED TO OLDER PHYSICAL PLANTS THAT ARE LESS THAN STATE-OF-THE-ART AND COMPLETELY OUTSIDE THE PURVIEW OF OSHA PROTECTIONS AND SAFEGUARDS.

AT THE SAME TIME, DOE, THE AGENCY RESPONSIBLE FOR CONDUCTING AND MONITORING RESEARCH ON THE HEALTH EFFECTS OF RADIATION EXPOSURE IS THE SAME AGENCY RESPONSIBLE FOR OPERATING THESE NUCLEAR WEAPONS PRODUCTION FACILITIES. WORKER HEALTH AND SAFETY AND BUDGETARY AND PRODUCTION CONSIDERATIONS CAN BE -- AND OFTEN ARE -- COMPETING INTERESTS.

THE PERCEPTION OF CONFLICT OF INTEREST HAS BEEN FURTHER HEIGHTENED BY DOE RESPONSE TO RESEARCH THAT HAS FOUND INCREASED HEALTH RISKS. FOR EXAMPLE, IN 1977, DOCTORS THOMAS MANCUSO, ALICE STEWART AND GEORGE KNEALE PUBLISHED THE RESULTS OF A STUDY WHICH FOUND AN ASSOCIATION BETWEEN CANCER AND EXPOSURE TO LOW-LEVEL RADIATION. THEIR RESEARCH HAD BEEN CONDUCTED UNDER A DOE CONTRACT. HOWEVER, UPON PUBLICATION OF THE RESULTS, THE DOE MOVED TO IMMEDIATELY SEVER THE CONTRACT. SHORTLY THEREAFTER, SEVERAL PAPERS CRITICAL OF THE MANCUSO STUDY WERE PUBLISHED BY OTHER DOE-SPONSORED RESEARCHERS. EVER SINCE, EMPLOYEES OF DOE NUCLEAR OPERATIONS HAVE BEEN UNSURE OF THE EXTENT TO WHICH THEY CAN TRUST THE RESULTS OF DOE-SPONSORED HEALTH EFFECTS STUDIES.

TO FURTHER UNDERMINE WORKER CONFIDENCE IN DOE RESEARCH, THE DEPARTMENT HAS SINCE CONTRACTED PRIMARILY WITH GOVERNMENT OWNED AND OPERATED LABORATORIES FOR THE BULK OF ITS HEALTH EFFECTS RESEARCH. THESE CONTRACTORS, WHO INCLUDE THE OAK RIDGE ASSOCIATED UNIVERSITIES (ORAU), BATTELLE NORTHWEST LABORATORIES (BNL) AND LOS ALAMOS NATIONAL LABORATORY, HAVE STUDIED 12 DIFFERENT RADIATION-EXPOSED POPULATIONS. IN EIGHT OF THESE TWELVE STUDIES, SIGNIFICANT EXCESS DEATHS HAVE BEEN FOUND. AND YET, THE DOE AND ITS CONTRACT RESEARCHERS HAVE INSISTED ON CHARACTERIZING THEIR RESULTS AS "PRELIMINARY AND INCONCLUSIVE." DR. C.C. LUSHBAUGH, SUPERVISOR OF THE ORAU WORK, HAS STATED, "WE DON'T THINK ANYBODY SHOULD HAVE ALARM ABOUT THEM...WE JUST DON'T CONSIDER THEM SUBSTANTIVE CONCLUSIONS."

DOE HAS ALSO FUELED THE CONTROVERSY SURROUNDING THE ACCURACY OF ITS RESEARCH BY THE WAY IN WHICH IT INSISTS UPON HANDLING THE DATA FROM THESE STUDIES. CITING PRIVACY ACT CONSIDERATIONS, DOE CONSISTENTLY DENIES RESEARCHERS DIRECT ACCESS TO THE RAW, OR SOURCE, DATA. RESEARCHERS RECEIVE DATA WHICH EXCLUDES IDENTITIES OF THE SUBJECTS OF THE STUDY, AND WHICH COULD REFLECT NO MORE THAN WHAT DOE WANTS THE RESEARCHERS TO SEE. THE ONLY INDIVIDUALS WITH ACCESS TO THE ACTUAL SOURCE DATA ARE THE PLANT OPERATORS AND THE GOVERNMENT-SPONSORED CONTRACTORS. AS A RESULT, IT IS IMPOSSIBLE FOR AN INDEPENDENT RESEARCHER TO REPLICATE OR VERIFY A DOE-SPONSORED STUDY.

FINALLY, DOE HAS FURTHER WEAKENED ITS CASE BY REFUSING TO ALLOW LABOR REPRESENTATION ON ITS ADVISORY AND PEER REVIEWS COMMITTEES WHICH MERELY SERVES TO UNDERSCORE THE DOUBTS OF THOSE WHO ARE THE MOST VULNERABLE AND DIRECTLY AFFECTED.

EVEN IF THE DEPARTMENT OF ENERGY WERE CONDUCTING GENUINELY OBJECTIVE, SCIENTIFIC RESEARCH -- AND IT MAY WELL BE -- THE WAY IT HAS HANDLED PAST STUDIES AND THE FINDINGS OF RECENT WORK HAS RAISED IMPORTANT QUESTIONS ABOUT ITS ACCURACY AND IMPARTIALITY. WHERE INCREASED INCIDENCE OF CANCER OR OTHER HEALTH PROBLEMS ARE FOUND OR EVEN INDICATED, DOE SHOULD BE BOTH FORTHCOMING WITH THAT INFORMATION AND QUICK TO OUTLINE HOW IT PLANS TO RESPOND. A FEDERAL AGENCY WITH NATIONAL RESPONSIBLITIES SHOULD NEVER CAVALIERLY DISMISS THE KINDS OF STATISTICAL INDICATORS OF RISK WHICH HAVE BEEN REPEATEDLY DISCOVERED AS NO CAUSE FOR "ALARM." THE RESULTING IMPRESSION OF CONFLICT OF INTEREST, AT LEAST IN THIS CASE, HAS IRREVOCABLY

DAMAGED DOE'S CREDIBILITY WITH THE PUBLIC AND WITH ITS WORKERS.

RESEARCH INTO THE HEALTH EFFECTS OF RADIATION EXPOSURE MUST BE CONTINUED. WE MUST NOT RELENT IN OUR SEARCH FOR ANSWERS. HOWEVER, IT IS ABSOLUTELY CRUCIAL THAT THIS RESEARCH BE CONDUCTED IN AS OBJECTIVE A MANNER AS POSSIBLE. THE PUBLIC AND THE DOE EMPLOYEES DESERVE TO HAVE THE FULL CONFIDENCE IN THE ANSWERS THAT ARE FOUND. AND, THEY SHOULD BE ABLE TO TRUST THAT APPROPRIATE ACTIONS WILL BE TAKEN TO SAFEGUARD THEIR WELL-BEING.

THERE IS LITTLE QUESTION THAT WE HAVE YET TO ACHIEVE A NATIONAL CONSENSUS ABOUT RADIATION EXPOSURE AND ITS POTENTIAL HEALTH EFFECTS. SOME IN THE SCIENTIFIC COMMUNITY HAVE SUPPORTED THE WORK OF THE DEPARTMENT OF ENERGY AND SOME HAVE ROUNDLY CRITICIZED IT. MR. CHAIRMAN, IT IS IMPORTANT TO UNDERSTAND THAT THIS LEGISLATION DOES NOT ATTEMPT TO PASS JUDGEMENT ON THE VALIDITY OF DOE'S EFFORTS IN THIS REGARD. RATHER, THE ONLY ISSUE WE ARE ADDRESSING TODAY IS WHETHER ANYONE CAN OR WILL HAVE CONFIDENCE IN RESEARCH CONDUCTED BY AN AGENCY WITH SUCH A HEAVY INVESTMENT IN THE OUTCOME.

IN THIS AREA, I BELIEVE THAT DOE HAS FAILED. IT HAS CONSISTENTLY CHOSEN COURSES OF ACTION WHICH HEIGHTEN, RATHER THAN ALLAY, FEAR AND SUSPICION. IT HAS CANCELLED CONTRACTS FOR RESEARCH WHICH HAS NOT PRODUCED RESULTS FAVORABLE TO DOE AND THEN ATTEMPTED TO DISCREDIT THE RESEARCHER. IT HAS OPTED TO INTERPRET FINDINGS OF INCREASED RISK AS INSUBSTANTIAL AND INCONCLUSIVE. IT HAS ADOPTED DATA ACCESS POLICIES WHICH PRECLUDE INDEPENDENT VERIFICATION OF STUDY RESULTS. IT HAS CLOSED ITS ADVISORY AND PEER REVIEW ACTIVITIES TO PARTICIPATION BY THE WORKERS WHO ARE MOST VULNERABLE AND DIRECTLY AFFECTED. THIS IS A DEFENSIVE POSTURE THAT INDICATES SOMETHING NEEDS TO BE HIDDEN FROM VIEW. IT IS NO WONDER THAT MANY IN THE SCIENTIFIC COMMUNITY AND IN THE RANKS OF THE EMPLOYEES ARE DOUBTFUL OF THE RELIABILITY OF DOE-SPONSORED HEALTH EFFECTS RESEARCH.

I BELIEVE THAT IT MAKES BETTER PUBLIC AND SCIENTIFIC POLICY FOR AN AGENCY RESPONSIBLE FOR HEALTH ISSUES TO HAVE AUTHORITY TO CONDUCT RESEARCH INTO THE HEALTH EFFECTS OF RADIATION EXPOSURE. THIS WOULD ANSWER THE CONCERNS OF MANY CRITICS WHO FEEL THE CONFLICT OF INTEREST CATEGORICALLY PRECLUDES ANY POSSIBILITY OF OBJECTIVE RESEARCH. IT WOULD ALSO ADDRESS THE CONCERNS OF THOSE WHO BELIEVE THAT AN AGENCY RESPONSIBLE FOR OPERATING ENERGY AND DEFENSE PROGRAMS SHOULD NOT HAVE ABSOLUTE AND FINAL JURISDICTION OVER THE HEALTH AND SAFETY OF WORKERS.

THIS IS THE REASON THAT OSHA WAS FOUNDED: TO PROTECT WORKERS IN PRIVATE INDUSTRY WHEN IT BECAME EVIDENT THAT MANY INDUSTRIES COULD NOT BE COUNTED UPON TO PROTECT THEIR OWN WORKERS. IN THE CASE OF NUCLEAR WEAPONS PRODUCTION, THE STAKES ARE TOO HIGH AND THE RISKS ARE TOO GREAT NOT TO TAKE EVERY POSSIBLE PRECAUTION TO ENSURE THE HIGHEST DEGREE OF SAFETY AND SECURITY.

IN 1979, PRESIDENT CARTER CONVENED AN INTERAGENCY TASK FORCE ON IONIZING RADIATION UNDER THE CHAIRMANSHIP OF THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE (NOW HHS). AFTER A THOROUGH REVIEW OF THE SITUATION, THE TASK

FORCE ISSUED A SERIES OF RECOMMENDATIONS, ONE OF WHICH WAS TO TRANSFER DOE'S RADIATION HEALTH EFFECTS RESEARCH TO A FEDERAL PUBLIC HEALTH AGENCY. UNFORTUNATELY, THIS RECOMMENDATION WAS LOST IN THE RE-SHUFFLING WHICH OCCURRED AFTER THE ELECTION OF 1980.

NONETHELESS, IT WAS ECHOED IN A REPORT ISSUED IN 1983 BY THE ROCKY FLATS BLUE RIBBON CITIZEN'S COMMITTEE, CONVENED BY MYSELF AND GOVERNOR LAMM OF MY OWN STATE OF COLORADO, WHICH CALLED FOR AN INDEPENDENT AND OBJECTIVE INQUIRY INTO THE HEALTH EFFECTS OF RADIATION.

FINALLY, IN 1984, SPURRED BY THE GROWING CONTROVERSY OVER THE RELIABILITY OF DOE-SPONSORED RESEARCH AND IN PARTICULAR BY THE COMPLETION OF A STUDY OF ROCKY FLATS WORKERS, GOVERNOR LAMM CONVENED AN IMPARTIAL AND HIGHLY RESPECTED PANEL OF SCIENTISTS AND PUBLIC HEALTH OFFICIALS TO REVIEW RESEARCH COMPLETED BY DR. GEORGE VOELZ AND OTHERS OF THE LOS ALAMOS NATIONAL LABORATORY. THAT RESEARCH LOOKED AT THE POTENTIAL LINK BETWEEN WORKING AT THE ROCKY FLATS NUCLEAR WEAPONS PRODUCTION FACILITY IN COLORADO AND A REPORTED INCREASE IN THE INCIDENCE OF BRAIN CANCER. THE PUBLISHED RESULTS OF THAT STUDY INDICATED NO SUCH LINK, DESPITE STRONG STATISTICAL EVIDENCE, AND COLORADO CITIZENS DEMANDED TO KNOW WHY.

THE REPORT OF THAT PANEL, THE ROCKY FLATS EMPLOYEES HEALTH ASSESSMENT GROUP, IDENTIFIED SEVERAL CRUCIAL METHODOLOGICAL PROBLEMS WHICH SKEWED THE RESULTS. ULTIMATELY, THEY INCLUDED AS ONE OF THEIR PRIMARY RECOMMENDATIONS, THE FOLLOWING STATEMENT:

"THE COMMITTEE BELIEVES THAT CARE SHOULD BE TAKEN TO ENSURE THAT IN THE NEXT ITERATION OF ROCKY FLATS CANCER STUDIES -- STUDIES WHICH COULD HAVE RESULTS WITH POLITICAL AND ECONOMIC CONSEQUENCES TO VARIOUS PARTIES AND ENTITIES -- INDIVIDUALS AND ORGANIZATIONS WITH POLITICAL AND ECONOMIC STAKES ARE NOT IN A POSITION WHERE THEIR JUDGEMENT MIGHT BE SWAYED, OR BE PERCEIVED TO BE SWAYED, BY SUCH CONSIDERATIONS. THESE DIFFICULT QUESTIONS CANNOT BE FULLY SEPARATED FROM THE ADAGE, 'HE WHO PAYS THE PIPER CALLS THE TUNE.'"

THIS IS THE TASK BEFORE US, AND I URGE THIS SUBCOMMITTEE TO CONTINUE MOVING TOWARD THIS CRITICALLY IMPORTANT GOAL.

THANK YOU, MR. CHAIRMAN.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

TESTIMONY BY

DR. DONALD IAN MACDONALD

ACTING ASSISTANT SECRETARY FOR HEALTH

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT FOR THE RECORD

SUBCOMMITTEE ON ENERGY, NUCLEAR PROLIFERATION AND GOVERNMENT PROCESSES

COMMITTEE ON GOVERNMENTAL AFFAIRS

U.S. SENATE

JUNE 17, 1986

I am Dr. Donald Ian Macdonald, Acting Assistant Secretary for Health of the Public Health Service in the Department of Health and Human Services (DHHS). I am pleased to submit testimony for the record on S. 525, "to transfer to the Secretary of Health and Human Services the authority of the Secretary of Energy to conduct epidemiological studies of the effects of radiation, and for other purposes."

In summary, the Department opposes enactment of S. 525. I will begin by stating our reasons for opposing the bill and follow with a description of our activities as they relate to radioepidemiologic research.

REASONS FOR OPPOSING S. 525

The Department of Energy (DOE) is responsible for the operation of numerous National Laboratories including the Argonne National Laboratory, Brookhaven National Laboratory, Lawrence Berkeley Laboratory, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, Oak Ridge National Laboratory, and the Pacific Northwest Laboratory. All of these labs conduct extensive radiation related research, much of which would continue whether or not DOE's health effects studies were to be transferred to DHHS. Thus transfer of DOE's radiation health effects studies to DHHS could represent a significant duplication of effort and would be unnecessarily disruptive. DHHS would have to establish the laboratory capabilities needed to assume responsibility for this research and yet the DOE laboratories mentioned above would continue to be maintained by DOE for other DOE research such as development of high energy particle accelerators, and for the development and testing of nuclear weapons.

The National Academy of Sciences, in two reports* it prepared concerning DOE research, generally commended the work done by DOE on the health effects of ionizing radiation. DOE epidemiological work is performed by contractors supervised by university scientists and the findings are published in peer-reviewed journals. The DOE, like the DHHS, funds epidemiological research but does not control the findings or publications. Although a conflict of interest on the part of DOE has been alleged periodically, DHHS believes that there is no evidence of any scientific conflict of interest on the part of the DOE nor are we aware of any documentation for these claims that would justify a transfer. If Congress believes the current placement of authority has created public doubt about the objectivity or scientific quality of these DOE studies, a better remedy than transferring the authority to HHS would be to require an outside scientific advisory body to oversee these studies. Meetings of such a scientific body should be public and should serve to mitigate public concern.

Continued responsibility by the DOE for the Radiation Effects Research Foundation (RERF) A-bomb survivor studies is essential to the ongoing research efforts in this area. Accurate dosimetry is essential to the success of these studies and is a unique capability found only in the joint and coordinated

* Federal Research on the Biological and Health Effects of Ionizing Radiation (FREIR), 1981, National Academy of Sciences; Review of Department of Energy Research on Human Health Effects of Low Doses of Ionizing Radiation, 1980, National Academy of Sciences.

efforts of the national laboratories maintained by DOE; the very large study to reassess the exposure of persons in Hiroshima and Nagasaki could only have been carried out with these resources, resources that would not be transferred to HHS. It also should be noted that the personnel who contribute to the A-bomb dosimetry have other duties and are widely scattered throughout the national laboratories and among other DOE contractors. DHHS would not have been able to mount the massive effort required for the current revision of the A-bomb dosimetry and would have needed to rely on the DOE with its resources of classified information and its control of the necessary expertise. Further, much of the programmatic leadership provided by DOE, through membership on the RERF Board and the Scientific Council, involves people who would not be transferred, such as high-level officials for whom RERF is important but is only one of their responsibilities. Finally, there are components of the RERF studies which do not fall naturally within the missions of the various agencies of the Department.

The current coooperation with the government of Japan on radiation studies would be severely disrupted by transferring the DOE's authority for the radiation effects studies to HHS. The Department of Energy and its predecessor agencies (AEC, ERDA) have negotiated with the Japanese government regarding the terms under which the original Atomic Bomb Casualty Commission (ABCC) studies were conducted. At the time the ABCC was replaced by the RERF, the terms of mutual support and management under which the RERF would function were negotiated by DOE. Consequently, much trust, confidence and understanding regarding administrative, programmatic and fiscal issues has been developed between the DOE and the Japanese Government. These would not readily transfer to HHS.

DEPARTMENT ACTIVITIES

The Department of Health and Human Services conducts radioepidemiologic research through three agencies of the Public Health Service: the Centers for Disease Control (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). The Fiscal Year 1986 HHS budget for our radiation epidemiology studies is $5,508,805.

CENTERS FOR DISEASE CONTROL

The Centers for Disease Control serves as the Department's focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States. Its overriding goal is prevention of unnecessary illness and premature death. Within CDC, the National Institute for Occupational Safety and Health (NIOSH) and the Center for Environmental Health (CEH) conduct epidemiological studies on workers and other groups exposed to radiation.

NIOSH is mandated through the Occupational Safety and Health Act to conduct epidemiologic studies in general industry and through the Federal Mine Safety and Health Act to conduct such studies in mining. The Acts provide right-of-entry into workplaces and access to records relating to workers and working conditions. The Acts also require NIOSH to conduct field evaluations in response to a request from employees or employers for an investigation of working conditions. Under Federal Executive Order 12196, NIOSH can also respond to requests for assistance from Federal employees (or their

representatives) or from Federal agencies. However, to respond to these requests, NIOSH requires the cooperation of the Agencies or their contractors to obtain access to the facility and access to records regarding that facility.

Although NIOSH has considerable experience in conducting workplace mortality and medical studies, it has limited experience and capabilities in monitoring occupational radioactive exposures. Most of the NIOSH epidemiologic effort is directed toward measuring and determining the effects of worker exposures to hazardous physical and chemical agents such as asbestos, benzene, and ethylene oxide. The radioepidemiologic studies described below are only a small part of the overall NIOSH program.

In the largest such study, NIOSH has evaluated the risk of cancer and other diseases among 4,142 uranium miners and 2,002 millers. This research began in the early 1960s and has been updated periodically since that time. It has provided valuable information, particularly about the risk of developing lung cancer from exposure to radon daughters. Current research efforts are designed to determine the cancer risk for miners receiving low level radon exposures and to evaluate the relationship between cigarette smoking and radon exposure in causing lung cancer among miners. NIOSH, working with the National Cancer Institute (NCI), is also studying the use of sputum cytology to screen these miners for lung cancer. Findings from this research have been used to help set standards for workplace exposure of uranium miners and millers and to provide guidance for minimizing the possible risks from exposure to radon daughter in homes.

NIOSH also has studied the adverse health effects of uranium exposure at various facilities that handle uranium compounds. The Institute is currently completing a mortality study of 5800 workers at a Department of Energy (DOE) facility in Piketon, Ohio. Workers at this facility are exposed to radiation during a uranium-enrichment process. The study, which began in 1979, has included an extensive survey of exposure to radiation at the facility and an epidemiologic follow-up of these workers. NIOSH is also currently analyzing data from another large medical study of workers at the DOE uranium-enrichment facility in Fernald, Ohio. This study includes tests of kidney function and respiratory function among 150 workers there. In addition, NIOSH has assisted in evaluating workers at this facility exposed to uranium dust from accidental releases inside the plant.

NIOSH has recently completed a large cohort mortality study and two case-control evaluations of 24,545 workers regarding possible cancer risk from radiation exposure at a naval shipyard. The Institute initiated this research in 1979 in response to concern about a possible excess incidence of leukemia among civilian employees at the shipyard. The mortality study showed no excess of leukemia related to radiation exposures. Although a possible excess incidence of lung cancer was found, this was not clearly related to radiation exposures and was probably related to other smoking or exposures at the shipyard (e.g., asbestos and welding by-products).

Mr. Chairman, in your letter regarding the topics to be covered by my testimony, you asked what priority HHS would give to the DOE worker health and mortality studies, should they be transferred to HHS. If S. 525 were enacted, worker health and mortality studies would probably be transferred to NIOSH

which has primary responsibility for occupational health research. The priority given to these studies would be determined through the Institute's current system for establishing research priorities for new projects. This system weighs such factors as the severity of the hazard in terms of potential harm to workers' health; the number of workers potentially exposed, currently and in the future; the adequacy of any existing regulations; knowledge of ongoing research; gaps in knowledge of exposure, severity of the hazard, and other critical areas; and existing levels of exposure. The DOE radiation studies would be evaluated along with other proposed new research projects under this system.

The Center for Environmental Health (CEH) at CDC has responsibility in three areas related to radiation: (1) the coordination of PHS/HHS responses to domestic radiation emergencies and participation in radiation emergency exercises at both the Federal and State level; (2) the provision of consultation and the conduct of epidemiologic studies on radiation-related health problems; and (3) participation in radiation-protection activities for CDC employees and the public. Radiation-protection activities include: planning and preparing to respond to emergencies; preventing hazardous radiation exposures when an accident occurs; reducing radiation exposure of persons in the vicinity of hazardous waste sites and other natural or artificial radiation sources; and evaluating the health effects of radiation exposures occurring in these situations.

CEH is currently conducting a number of epidemiologic studies related to radiation. For example, a cohort of 3200 veterans exposed to one atomic test in the United States' atomic testing program is being followed up for cause of

death. CEH is also conducting studies to evaluate community exposures from past environmental releases at several DOE nuclear facilities (Oak Ridge, Tennessee; Savannah River Plant, South Carolina; Fernald, Ohio; and Hanford, Washington) and is assessing public risk from exposures to radiologic waste sites such as those found in Montclair and Glen Ridge, New Jersey. These latter assessments are not epidemiologic studies; they are evaluations of available monitoring information to determine the possible health risk for community residents from radiation at these waste sites. CEH is also involved in determining radiation doses from a small amount of radioactive gold that was made into gold jewelry and is known to cause skin cancer. In addition, CEH provides consultation to the Environmental Protection Agency and State governments on the public health risks of radon contamination in homes.

FOOD AND DRUG ADMINISTRATION

The primary mission of the FDA is to minimize health risks associated with foods, human and animal drugs, cosmetics, and medical devices. The FDA, through its Center for Devices and Radiologic Health, (CDRH), is in the process of completing a followup study of persons who received iodine-131 for diagnostic purposes during childhood. The purpose of this study is to determine whether diagnostic doses of iodine-131 are associated with thyroid tumor induction. The study is a multi-institutional followup of approximately 6,500 persons who, as children or adolescents, received diagnostic iodine-131 for tests of thyroid function between 1945 and 1967. The data collection and processing are performed under contract; management and analytical functions are performed by CDRH. During 1985, data collection on this project was completed. In 1986, the Center expects to complete the remaining phases, including analysis, of the study.

THE NATIONAL CANCER INSTITUTE, NIH

The NIH's National Cancer Institute (NCI) is the Federal Government's principal agency for conducting research on cancer. The mission of the NCI is to conduct and support research, training, health information dissemination and related programs with respect to the cause, diagnosis, prevention, and treatment of cancer and the continuing care of cancer patients and the families of cancer patients.

The NCI plans and directs a national program of basic research including laboratory, field, and epidemiologic and biometric research on the cause and natural history of cancer and means for preventing cancer. A small radiation exposure and health effects research effort is included within the Institute's activities. It should be noted that while the NCI studies the link between radiation and the development of cancer, the Institute does not study potential or actual effects of radiation other than cancer.

NCI is conducting studies investigating the health effects of ionizing radiation used in medical treatments of children such as tonsil irradiation, irradiation for ringworm, and the risk of childhood leukemia in individuals with prenatal exposure to radiation. NCI has also conducted studies to evaluate the risk of developing a second cancer among children and adults receiving radiotherapy or chemotherapy.

NCI is currently investigating the health effects of exposure to diagnostic x-rays, including those used to identify scoliosis, and investigating the health effects of multiple chest fluoroscopies of tuberculosis patients and fluoroscopies for heart catherization.

NCI is collaborating on studies of the effects of radiation on workers including studies of the effect of radiation on x-ray technologists in the United States and in China. In addition, NCI is conducting a study evaluating the possible risk of lung cancer associated with radon exposure in the home and a study of thyroid cancer possibly associated with high background radiation levels in China.

The NCI has also collaborated on incidence and case-control studies of cancers of the breast, colon, rectum, and thyroid among atomic bomb survivors. In Utah, the NCI is supporting studies to assess the incidence of both leukemias and thyroid cancer in relation to radioactive fallout resulting from atmospheric testing of nuclear weapons at the Nevada Test Site.

PLACEMENT OF STUDIES

Finally, Mr. Chairman, you asked about the placement of the individual DOE radiation epidemiologic studies within HHS, should the responsibility for these studies be transferred. The transferred studies would be distributed among the public health agencies involved— CDC, NIH, and FDA. A detailed analysis of each individual DOE study would have to be conducted to determine where each study would fit within the missions of the respective agencies. This decision would also depend on each agency's involvement in specific radioepidemiologic research, and each agency's scientific expertise at the time of the transfer.

That concludes my statement, Mr. Chairman. Thank you for the opportunity to submit comments for the record on this important issue.

Statement of Arthur C. Upton

Professor and Director
Institute of Environmental Medicine
New York University School of Medicine

to the

Subcommittee on Energy. Nuclear Proliferation
and Government Processes

Concerning S525

"The Radiation Reorganization Act of 1985"

Hearing, June 17, 1986

Statement for the Record, May 5, 1986

63-490 O - 86 - 9

Mr. Chairman and Members of the Subcommittee:

I am grateful to you for the opportunity to present my views on S515. the Radiation Reorganization Act of 1985. As a scientist who has devoted much of his career to the study of radiation injury, I am fully convinced of the need for a strong national research effort in radiation epidemiology.

Since the first report of the Federal Radiation Council, in 1960, which recommended abandonment of the threshold hypothesis for purposes of radiological protection, there has been continuing concern about the potentially harmful genetic, carcinogenic. and teratogenic effects of small doses of radiation such as are received by the general population from natural background irradiation. atomic weapons fallout. medical radiography, nuclear power, and various other sources. Research has thus been directed increasingly toward the assessment of such risks. To expedite the research, and to assure that it is timely, vigorous, well conceived. and well balanced. the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) has been charged with responsibility for evaluating and coordinating the relevant efforts of the various Federal agencies.

I am not an epidemiologist myself, but I have closely followed epidemiologic research on the effects of radiation in human populations for more than 30 years, and I know the contributions to the field that have been made by various institutions in this country and elsewhere in the world. To my knowledge, the research contributions of all other national and international agencies combined do not approach. in quantity or quality, those of the DOE and its predecessors, AEC and ERDA. The follow-up of the a-bomb survivors by the Radiation Effects

Research Foundation constitutes only one of many examples of DOE's outstanding leadership in this important subject area.

DOE's epidemiological research program has been repeatedly peer-reviewed and has included studies of virtually every type of irradiated population; e.g., a-bomb survivors, Marshall Islanders exposed to fallout, radium dial painters, patients exposed to external or internal radiation for diagnostic or therapeutic purposes, radiologists, radiologic technicians, infants exposed prenatally during the radiographic examination of their mothers, uranium miners, nuclear plant workers, and various other populations. In short, the study of these populations under the sponsorship of AEC, ERDA, and DOE has provided the bulk of existing information about the effects of radiation on human health.

As an agency responsible for the safety of its employees and other population groups which may be exposed to ionizing radiation, it is appropriate for DOE to sponsor the research needed to define the health effects of low-level irradiation. Ideally, such research should comprise studies at all levels of biological organization, as was emphasized by GAO in its recent review of the subject, including epidemiological follow-up and surveillance of DOE employees and other populations. The results of such studies are essential to DOE for the validation of risk assessments, exposure standards, and operating procedures. The studies might not command the same commitment or priority in another agency.

In summary, I find no basis for faulting DOE's epidemiological research program on the basis of its scientific accomplishments. On the contrary, its productivity has been outstanding. Tranafer of the

program at this time would be disruptive to the research without necessarily improving its performance.

Statement of Warren K. Sinclair

President

National Council on Radiation
Protection and Measurements

to

the Subcommittee on Energy Nuclear Proliferation and
Government Processes

of the

Senate Committee on Governmental Affairs

Concerning S. 525

"The Radiation Reorganization Act of 1985."

Hearing, June 17, 1986

Statement for the Record, May 5, 1986

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to present my views on S 525, the Radiation Reorganization Act of 1985. I must emphasize that I will be expressing my personal views arising out of my experiences as a senior scientist and administrator (Associate Laboratory Director) at one major DOE laboratory (Argonne National Laboratory in Chicago), (1960-1981) and from my experiences as President of the National Council on Radiation Protection and Measurements (NCRP) (1977-) and as a member of the International Commission on Radiological Protection (ICRP), the International Commission on Radiation Units and Measurements (ICRU), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

The NCRP

By way of background, I should, perhaps, provide some information about the NCRP. The NCRP is a not for profit corporation, chartered by the Congress to ". . . collect, analyze, develop and disseminate in the public interest information and recommendations about (a) protection against radiation and (b) radiation measurements, quantities, and units, particularly those concerned with radiation protection . . . " Its aim is to promote better radiation protection for the public and for radiation workers, and to provide to Government and others, expert advice on measurements and effects. It also provides, to those utilizing radiation in their work, such as in medicine, in industry and in environmental circumstances, guidance on safe practices. The Council has 75 full members and 500 additional committee members drawn from all relevant branches of science and medicine related to radiation protection in the USA. These persons serve voluntarily and their main function is to produce carefully reviewed reports which assess the state of knowledge in all fields of radiation research relevant to radiation protection and from these assessments render professional advice and guidance for the use of federal agencies and other legal bodies, as well as for the public, radiation workers, and professional users. The international bodies referred to perform similar functions on an international scale.

I turn now to the Bill, which I understand would bring about a transfer of responsibility for radiation epidemiology from the Department of Energy to the Department of HHS. While I have the greatest respect for Senator Glenn, I am opposed to the Bill because I do not believe the proposed transfer is justified, nor does it address what seems to be the real problem at issue, as I shall explain below.

The DOE-OHER Program

The Department of Energy (DOE), through its Office of Energy Research, and specifically the Office of Environmental Health and Safety (OHER), has maintained a research program in all phases of radiation research relevant to biological effects for almost forty years. This research program has examined and continues to study the biological effects of all forms of ionizing radiation in living systems extending from molecules and cells to plants and

animals, as well as relevant studies in human beings where available. The integrated nature of this program and its utilization of scientists of many disciplines is among its most important assets. A milieu in which interactions between scientists of different backgrounds can flourish has been especially fruitful in dealing with such cross disciplinary problems as radiation effects. Epidemiology embedded in such a milieu can take advantage of directly known facts in a variety of other fields to more fully assess the effects of exposure in human beings.

In the case of epidemiology, not only is the association with other biological programs important, but epidemiological assessments depend heavily on the dosimetry ascribable to the affected population, indeed their dosimetry is the denominator in the risk equation. Dosimetry and its base in pure physics is the unquestioned domain of many of the DOE laboratories and to separate the epidemiology from its dosimetry base in any administrative way would seem to be an extremely retrograde step.

Laboratory Peer Review

The vast amount of experimental, theoretical and epidemiological work conducted by DOE is peer reviewed and published in the open scientific literature. It is important to appreciate also that the major laboratories involved in this program are operated by contractors, most of whom, like the University of Chicago and the University of California, have long established reputations of independence of thought and action. The employees of these laboratories owe their employment and their loyalty to the laboratory itself, or the contractor, rather than the more distant DOE, which, however, of course, has the national responsibility for programs at the laboratories. The contractors generally maintain peer groups for each of a given laboratory's scientific divisions, which meet annually, examine all reports of programs and procedures, including the published record of peer reviewed papers and render reports on their findings to the contractor. Actions for improvement, modification, or initiation of new programs and other changes, usually develop from the laboratory and the contractor, perhaps in consultation with DOE-OHER. Membership of these peer groups is drawn from the professional ranks of the Universities and research institutions of the nation and rotates with time. In further addition to this, DOE-OHER sponsors topical reviews of their own at the laboratories, again bringing a different set of peers to each of the laboratories to examine progress in a given area of the field. The peer group usually produces a report on the state of that topic in the laboratories. I understand that there was recently such a peer review report on the DOE-OHER epidemiological programs and the report is available at DOE-OHER.[1] Over and above this steady and continuous review system, there have from time to time been special overall reviews of selected phases of the DOE biological (or human effects) programs, such as that conducted by the National Academy of Sciences Committee on Federal Research on the Effects of Ionizing Radiation (FREIR Committee). This committee produced, after a 2-year study, a published report in 1981.[2] I have dwelt on this matter in some detail to represent to the Committee the extent and the thoroughness of the peer review of this part of the DOE program. As a result, I believe DOE-OHER programs are

successfully monitored and guided with the best scientific advice available in the country and I feel confident that their scientific credibility is above reproach.

The Japanese epidemiological studies

While, it seems to be adequate worker protection and understanding that is at issue, it is the epidemiological studies that are to be transferred. However, only part of the DOE epidemiological studies involve workers and, indeed, the worker studies have not been especially helpful with respect to risk estimation. Others, and certainly the most important from the point of view of epidemiological information relating to risk, involve entirely different study populations. Among the most important are the studies evaluating exposures in the Japanese survivors of the atomic bombs, operated by DOE through the National Academy of Sciences and the joint U.S.-Japan Radiation Effects Research Foundation. To transfer this study would, indeed, be totally unjustified. To interfere organizationally and structurally with such important long-term studies, 40 years in the making, could only be retrograde and could have very serious impacts on the entire program.

Furthermore, the recent revisions in the dosimetry of the Japanese survivors which have resulted from a very extensive effort by mainly DOE (and DOD) laboratory personnel, could not have been mounted in the same way by another agency. This effort has clearly demonstrated how closely linked is the assessment of biological damage and the dose responsible for it, in epidemiological work -- and also how important that dosimetry base in the DOE laboratories has been. These Japanese studies are of enormous importance to everyone, worldwide, and especially to the professional bodies, national and international, who rely on the information from the Japanese as a major part of the human experience with ionizing radiation. To interfere with the tried and true management of this highly successful program administratively forged between DOE and Japan over many years is simply not warranted by the circumstances.

Epidemiological studies and national and international bodies

Much of what we know in the world today about the effects of radiation stems from the studies in DOE laboratories and other similar studies. National and international bodies, such as NCRP, ICRP, NAS and UNSCEAR, involved in assessing the results of such studies and their application to the radiation protection of workers and the public rely heavily on the scientific output of the DOE laboratories, as well as on that of the Universities and other scientific laboratories in this country and around the world.

Because the effects of low levels of ionizing radiation are difficult to distinguish from the natural level of somatic and genetic effects occurring in human populations (including the effects of natural background radiation), radioepidemiological studies of such effects after low doses are fraught with many difficulties and uncertainties and consequently some debate can arise over their interpretation. Radioepidemiological studies undertaken by DOE are subject to these limitations also, but no scientifically valid criticism of

the DOE studies has been sustained. Indeed, the proposed transfer includes the transfer of personnel and, therefore, presumably does not imply criticism of how past studies were done. National and international bodies accept the validity of DOE studies as being at least equal to other sources of scientific information. They keep a very watchful eye on all sources of data involving humans, as well as on other results of radiation research, that can contribute to a quantitative understanding of the risks of radiation exposures to human beings.

The Transfer is not Justified

Why do I believe the proposed transfer is not justified? First, the cost in time and money are much greater than anyone external to the management of a large scientific laboratory can possibly imagine. Transfer of programs between agencies involve changes in operating practices and administrative hierarchies for that program only, which are confusing to scientific personnel and require time and diverted effort to adjust to. For the laboratory, it means a special set of different operating procedures for this one (small) program embedded in a large laboratory with already established procedures and practices that have worked successfully for it. In the meantime, the very studies at issue and still ongoing inevitably suffer from delays at the very least, if not worse.

Second, the risk of damage to the scientific conduct of the programs due to separation from the current milieu of other radio-biological research, dosimetry studies and the like, is simply not worth taking. To isolate the epidemiological studies within such a laboratory by administering it through a different agency or even worse, to transfer it away from its present desirable milieu, is surely not a step in the right direction.

Problems of perception

The primary reason given for the transfer is the perception that the studies are biassed by the unfavorable influence of DOE as an employer. This seems to be particularly true of studies involving workers in some DOE plants and perhaps especially those involving production elements rather than research. I sympathize with workers who feel they are not being adequately protected or informed in relation to the relatively sophisticated practices of handling radioactive and other nuclear materials. Every effort should be made to ensure that not only actual standards of safety, but perceived standards of safety are truly as high as they can reasonably be. Indeed, the systems of protection recommended by national and international bodies require justification of procedures, reducing exposures to the practicable minimum (ALARA), in addition to conforming to specified dose limits. DOE facilities are required to observe these rules and they appear to result in average exposures to workers which are some small fraction of the dose limits and only 2 or 3 times the natural background (EPA, 1984).[3] If this is not actually the case in a given plant, the DOE control system should quickly account for it. If it is perceived not to be the case when it actually is, that is a problem that must be resolved, but by appropriate methods. Appropriate methods might include not only major and sustained educational programs in the laboratories and plants themselves (which I believe some of them already have), and other procedures the laboratories and plants may adopt, but also external review of

protection procedures, methods, records of exposure by independent reviewers. If the protection systems are working well, such reviews might provide the necessary assurances over a period of time, to concerned workers. None of these problems will be solved by transferring epidemiological programs.

DHHS

There is no suggestion in these comments that DHHS, which already has ongoing epidemiological studies of its own, would not be able to perform the studies in excellent fashion if the transfer were to take place, but there is also no reason to suppose that the studies could be better performed there. Whatever limitations there are to such studies are, unfortunately, mandated by the data and these cannot be solved by changes in organizational structure.

Summary

In summary, in my opinion, the proposed transfer would cause many disruptions in work and practices at a number of DOE laboratories, potentially destroy important scientific interactions in those laboratories, including the union between biological damage and dosimetry and hamper the continued development of important information from such studies as those on the Japanese survivors for no essential benefit to anyone. Perception alone does not justify such a disruption. Perception of the adequacy of radiation protection is an important problem that should be dealt with positively and by appropriate means, but not by the transfer of radioepidemiological programs.

Mr. Chairman, respectfully, this is my opinion.

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[1] Review of the Office of Health and Environmental Research Program. Epidemiology. Subcommittee of HERAC, U.S. Department of Energy, Washington, D.C., September 1984

[2] Federal Research on the Biological and Health Effects of Ionizing Radiation. The FREIR Report. National Academy of Science Press, Washington, D.C., 1981.

[3] Occupational Exposure to Ionizing Radiation in the United States. EPA 520/1-84-005. U.S. Environmental Protection Agency, Washington, D.C.

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Health & Environmental Research

Summary of Accomplishments

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The purpose of this brief narrative is to foster an awareness of a publicly funded health and environmental research program chartered nearly forty years ago, of its contributions toward the national goal of safe and environmentally acceptable energy development, and of applications of its findings toward the improvement of human health. This program, administered by the Office of Health and Environmental Research, in short, OHER, is one of many research activities of the U. S. Department of Energy (DOE). Over the years this program has been sponsored by other federal agencies responsible for the national energy mission. Its evolution has been a reflection of changes in time, in public priorities, and in Congressional mandate. But, throughout this evolvement, there has remained a consistency of purpose: to seek a fundamental understanding of the health and environmental aspects of emerging energy technologies and to establish the body of knowledge necessary to the development and utilization of the technology consistent with the public health and safety.

The story of this research program can be told through its accomplishments. Several of the more significant of these accomplishments have been chosen here for illustrative purposes, including some whose value has far exceeded the cost of the research program itself. However, regardless of the measure of its economic benefit, the basic motivation for the program remains to *serve the public interest* through health and environmental research. In the few pages that follow, the selected accomplishments are grouped and reviewed within each of several areas of research.

Executive Summary

This is a short account of a 40-year-old health and environmental research program performed in national laboratories, universities, and research institutes. Under the sponsorship of the federal agencies that were consecutively responsible for the national energy mission, this research program has contributed to the understanding of the human health and environmental effects of emerging energy technologies. In so doing, it has also evolved several nuclear techniques for the diagnosis and treatment of human ills.

The form of this presentation is, literally, through "snapshots"—examples of significant, tangible accomplishments in each of these areas at certain times to illustrate the role and impact of the research program. The program's worth is not necessarily confined to such accomplishments; it extends, rather, to its ability to identify and help solve potential health and environmental problems before they become critical. This anticipatory mission has been pursued with an approach that combines a commitment to fundamental research that is long term and high risk with applied problem solving.

The narrative of this research program concludes with a perspective of its past and a prospectus on its future.

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Origins of the Research Program

The origins of the Office of Health and Environmental Research trace back to the outset of the Second World War and the establishment of nuclear research centers under the "Manhattan Project." The first formal program began in 1942 as a Health Division, established by Dr. Arthur Holly Compton, Director of the University of Chicago Metallurgical Laboratory. Already a Nobel Laureate for his work on X-ray scattering, Dr. Compton recognized the unprecedented hazards posed by radiation to wartime workers at the laboratory. With the perspective of a half century of earlier experience with X rays and radium, he and his colleagues could well appreciate the dangers as well as the possibilities of atomic radiation. Biomedical programs were soon established at Oak Ridge, Tenn., and in the Manhattan Project at large, and it is fortunate that these programs were able to attract the most competent physicians and medical researchers in the field of the biomedical effects of radiation.

Like the Curies and other pioneers in the field of radiation, those who sought to protect the health of their colleagues could understand, more than others, that the phenomenon that so concerned them was, at the same time, an opportunity. They grasped its significance and foresaw the promise of radiation and nuclear medicine as a new means for medical diagnosis and treatment. This promise has been fulfilled. Today nuclear medicines are produced and packaged in myriad forms and are in widespread use; for example, thallium-201 alone was administered to 370,000 patients in 1981 for the diagnosis of heart disease.

In providing the first legislative basis for the health research program through the Atomic Energy Act of 1946, the Congress overlooked neither the opportunities nor the dangers presented by radiation. In the act the Congress directed the Atomic Energy Commission (AEC) to

. . . make contracts, agreements, arrangements, grants-in-aid, and loans . . . for the utilization of fissionable and radioactive materials for medical and health purposes . . .

and for

. . . the protection of health during research and production activities . . . .

The need for a highly qualified group of research administrators was foreseen to fulfill this broad charter. Thus the Division of Biology and Medicine was established, and Dr. Shields Warren, Professor of Pathology at Harvard, was named its first director. Under Dr. Warren the division laid down the outlines of a vigorous research effort in fundamental studies in the life sciences, in applied areas to ensure industrial hygiene in AEC facilities as well as the public health and safety, and in fostering the rapid growth of nuclear medicine.

The responsibility for administering this program was later assigned to the Energy Research and Development Administration (ERDA), which succeeded the Atomic Energy Commission through the Energy Reorganization Act of 1974. The oil embargo, however, had underscored the need for developing a wide range of energy options and technologies in addition to nuclear, and this was reflected in the new agency's mission. Therefore this act charged the ERDA administrator with the additional responsibility of

. . . engaging in and supporting environmental, physical, and safety research related to the development of energy sources and utilization technologies.

These responsibilities were assumed by the agency's Division of Biomedical and Environmental Research, which initiated a significant program of nonnuclear research, focusing on the development of fossil fuels and renewable energy sources. At the same time, a broad range of legislation* strengthened and expanded the rationale for ERDA's program of health and environmental research by establishing a regulatory framework by which the results of this research could be integrated directly into the planning and development of energy technologies.

Although the Energy Research and Development Administration was relatively short lived, these research functions were retained intact by the new Department of Energy, which was established in 1977. Within the Department of Energy, these responsibilities have been carried on by the Office of Health and Environmental Research.

What, then, has been the net result of OHER's history of changing roles and mandates? A central mission has evolved, requiring the integration of three fundamental areas of study: (1) the *source*, or the potentially toxic agent of concern; (2) its *transport*, or the path from its point of release; and (3) the *effects* that it could produce upon populations and on the environment.

The first of these areas involves the understanding and characterization of the material, pollutant, or agent of concern. Despite the seemingly limited scope of this phase of study, unexpected rewards of a much broader nature can result from this research. For example, the OHER mandate under the Atomic Energy Act required an understanding of radiations of various kinds and of their interactions. This in turn created a need for the development of a host of radiation detection instruments, some of which became essential to the field of nuclear medicine, as noted later.

The second facet of the mission, source transport, began as an effort to understand the paths that might be taken by radioactive materials through the environment. As the range of energy options under development increased, however, the transport of materials from other technologies, such as coal fly ash, combustion gases, and synthetic fuel components, also came under study.

The final segment of OHER's integrated mission is to determine the nature and the extent of the potentially toxic source materials on man and his environment. Once again, initial research in this area was confined to radiation biology—the study of mechanisms and magnitudes of effects produced by radiation. These studies included the uptake and distribution of radioactive materials in animals and in man to determine potential toxicity. This knowledge, when coupled with developments in nuclear instrumentation, provided the basis for the development of nuclear medicine, which was but one of the new directions in research to receive its impetus from radiation biology. The quest for answers to the mysterious response of cellular DNA to radiation spawned an unparalleled research program in basic genetics.

Thus the objective of the OHER mission has been straightforward—to perform fundamental research on the energy-related triad of *source–transport–effect* and to integrate its basic findings toward the solution of practical questions. The descriptions of program accomplishments that follow provide a glimpse of some of the more tangible products of this research process. But, with the background for the presentation of these products provided, some caveats are first in order.

As in any other research enterprise, there is a continuum of effort, and a "snapshot" of selected OHER program accomplishments can easily create a distorted view of the overall workings of the program. It has already been noted that, although many of the accomplishments described have proved to be of considerable economic importance, this occurrence is not necessarily a measure of the effectiveness of the research within the context of the OHER mission; nor is it a factor in shaping the OHER research agenda. The course of research is complex and can lead to a number of dead ends as well as to successes and breakthroughs. A seemingly fruitless effort can sometimes be useful, however, by virtue of its indication of more productive pathways, and one of the accomplishments described, which eventually ended in a treatment for Parkinson's disease, provides a case in point. Basic research, a key part of the program, is of a long-term nature and often contributes no immediately measurable benefit. Yet, even in the event of negative results, it adds incrementally to our storehouse of information, which, in itself, is a major accomplishment. The bone-marrow-transplantation work undertaken early in the program is an example of basic research which ultimately provided much of the information that underpins the current state of the art for organ-transplantation work in medicine.

Thus, in summarizing the accomplishments of a research program designed for a mission as far-reaching as that of OHER, one must take care to avoid judging its worth solely on the basis of economic benefit or immediate applicability. The result of research may be a tangible product (e.g., a nuclear scanner or a radiopharmaceutical) of readily calculable value. But the "product" may also be the answer to the riddle of self-repair to cell injury, the mechanism by which a particle is transported, or the definition of the risk of bone cancer from radiostrontium.

*This legislation, beginning with the National Environmental Policy Act in 1969, included the Clean Air Act, Safe Drinking Water Act, Toxic Substances Control Act, and the Resource Conservation and Recovery Act.

Thus it is equally valid to judge the benefit of a research contribution in terms of its reduction of uncertainty or its description of a previously unknown mechanism. These criteria have been in consonance with the energy development missions of OHER's parent agencies (AEC, ERDA, and DOE), which have made use of OHER research in an anticipatory manner to prevent, modify, or mitigate potential health and environmental effects before an emerging technology reaches maturity. The contrast between the anticipatory nature of the OHER research program and the research conducted by the regulatory agencies is readily apparent from the differing content and objectives of the respective research programs. The ultimate goal of the research program, therefore, is not so much to *find* effects as it is to aid in their *prevention*. The extent to which this goal is realized is the true measure of the program's benefit to the nation.

The following sections describe selected, definitive research contributions resulting from the OHER research program—accomplishments of the many individuals in national laboratories, universities, and research institutes who conduct this work under contract to OHER. In some instances the research has been cofunded or is now pursued under auspices other than OHER. Unfortunately, in a summary document of this size, it is not possible to give complete documentation or credit due to researcher, laboratory, and sponsor. A supplemental document of considerable length will be issued shortly which will provide such information as well as greater detail of the accomplishments themselves.

Emerging Energy Technologies

OBJECTIVE: Through Research, Examine the Potential for Adverse Effects on Human Health and the Environment from Emerging Energy Technologies.

It is the purpose of this Act . . . to advance the goals of restoring, protecting, and enhancing environmental quality and assuring public health and safety . . . .
—Sec. 102, Public Law 95-91

The functions which the Secretary shall assign . . . shall include . . . conducting a comprehensive program of research and development on the environmental effects of energy technologies and programs.
—Sec. 203, Public Law 95-91

Thus the Department of Energy Organization Act continued the charter of a predecessor agency, the Energy Research and Development Administration. Aside from including all energy technologies, the new act identified, for the Department of Energy, responsibilities for the public health and safety which were virtually identical to those of the Atomic Energy Commission in its nuclear development and production programs. In all three charters the intent of Congress was clear: to foster a better understanding of the potentially adverse effects on human health and the environment of emerging energy technologies. The dramatic dislocations following the oil embargo of 1973 gave impetus to the development of the emerging technologies—synthetic and renewable fuels as well as nuclear—and thus added to the urgency of these responsibilities.

Identification and Evaluation of Human Health Effects

Nuclear Technology The formal inception of the health and environmental research program under the Atomic Energy Commission also provided its primary focus: the study of the health effects of radiation exposure. There was more than sufficient reason.

At the outset of the Second World War, it was apparent that radiation could have adverse effects on human health. It was known that living cells could be damaged by radiation, and this phenomenon was already under study in many universities and hospitals throughout the world. The two atomic bombs detonated in wartime provided ample and tragic proof of radiation damage. The study of long-term effects of radiation on the survivors provided a wide range of dose-effect information of direct benefit to the emerging peaceful uses of the atom, including nuclear medicine and power applications. But, as we will see, in a much larger sense the study also marked the beginnings of research of the most fundamental kind, that which today holds great promise of a better understanding of biological processes and of treatments and therapies for a number of human diseases. The survivor study became an integral part of a broadly based program of research on radiation and its effects, ranging from observing the health of workers in nuclear and related industries over their lifetimes to conducting basic research to understand the fundamental processes that occur when human cells are damaged by radiation.

This research program has provided the information essential to the public debate on nuclear power. It has also provided the basis for setting radiation protaction standards which have undergone constant review since their initial formulation 33 years ago. Continuing studies have reaffirmed an awareness that exposure to all radiation should be kept low; over one million people, such as nuclear shipyard workers, are currently under observation to reduce uncertainties regarding low-level radiation effects. In addition to fulfilling its primary objective of providing the information necessary to protect the health of the public and of workers in radiation environments, the body of knowledge generated on radiation effects also finds practical use in court deliberations by providing a

scientific basis upon which claims of injury can be assessed and equitable decisions can be reached.

The radiation standards themselves, though sufficiently restrictive to protect the public health, have not imposed undue economic penalty on the technology on which it has the greatest impact—nuclear electric power. More-stringent standards, which might have been necessary in the absence of knowledge gained through the research program, could have easily cost electric power consumers an additional $2 billion annually.

It was stated earlier that research can lead to unexpected rewards. For example, research on Parkinson's disease, which originated in nuclear medicine, resulted in the discovery of a treatment that is entirely nonnuclear in nature. But perhaps no more dramatic example of unexpected benefit exists than the insights that have been gained into biological processes as the result of studies of the effects of low radiation doses. Areas that have benefited from the basic work in radiation biology include genetics and human evolution, immunology, causes of and treatment for cancer, and research on aging.

How did those seemingly unrelated benefits come together? It was already known by the early 1960's that healthy cells have ways to repair damage from certain radiations (e.g., ultraviolet). The repair, first demonstrated on exposed bacteria, was soon shown to apply to human cells. By the late 1960's, it was discovered that victims of a rare skin cancer lacked the ability to repair damage to their DNA, the substance that carries genetic information in cells. As scientists observed the effects of DNA damage, not only from a variety of radiations but also from chemical agents, it became more evident that the cell must possess a mechanism for repairing DNA. Subsequent study of the damage and repair mechanisms, and of the structure and alterations of DNA, led to a host of theories on the possible causes of genetic diseases, birth defects, aging, and cancer, as well as advances in immunology and treatment. Much of this research may eventually resolve the question of the existence of a threshold and the ultimate expression of radiation damage.

Synthetic Fuels The enhanced availability and production of domestic fuels, including synthetic fuels, have remained high in national priorities for many years. The health and environmental aspects of these new energy sources, however, have required investigation because synthetic gaseous and liquid fuels have compositions that can be quite different from those of their naturally occurring counterparts. Some organic compounds in these fuels have been linked to cancer, particularly those fuels consisting of single or multiple ring-shaped molecules (cyclic and polycyclic compounds) and including other elements in addition to hydrogen and carbon. This information is needed by those concerned with industrial hygiene and public health as well as those in process development and planning. On the industrial level, early recognition of the nature of potential risks can indicate the necessity for process modifications and controls to avoid premature commitment to fixed design and thus avoid the imposition of cost-ineffective regulatory strategies. The analysis of uncertainties in the knowledge of health and environmental risks also assists in identifying gaps and in ordering research priorities within the Department of Energy.

Several of the methods used to detect and to characterize the toxicities of synthetic-fuel components were developed within the research program of the Office of Health and Environmental Research and are described later. Briefly, a sequential strategy is employed which uses these tests in determining the toxicities of the large numbers of fuel-component samples to be evaluated. Generally the samples are first screened through a series of easily performed cellular bioassay tests to determine whether the compounds will alter or produce toxic effects in living cells. In practical terms, this involves the physical and chemical separation of the sample into component fractions, followed (typically) by a simple laboratory test of their toxicities. On the basis of these tests, chemical fractions that demonstrate high toxicity or biologic activity and potential for human exposure are tested to determine short-term and long-term toxicities in living animals by skin painting, inhalation, or ingestion. The more elaborate studies using laboratory animals are usually undertaken when the rapid, less costly screening tests indicate that there may be a potentially important human health problem. This, briefly, is the multitiered experimental approach in wide use today.

The ultimate objective of this research is to provide sufficient information for estimating the probability of producing a specified number of health effects in a population for a given exposure to the toxic agent. This draws heavily upon risk-analysis techniques, for it involves extrapolation of animal data to estimate implications of risk for humans. If the uncertainties in this process are large, further research is required.

What, then, have been the major accomplishments in this part of the research program? We now know that some of the compounds that could be encountered in synthetic-fuels manufacture are toxic and mutagenic and that they belong to specific groups of chemicals which now have been identified. This has led to a successful search in both industry and government for methods to alter or reduce the concentrations of these compounds wherever they may occur in synfuel processes. The research program has also focused attention on the need to develop additional data on the effects of the specific synfuels pollutants identified to be of primary

concern and on the pathways and mechanisms by which the pollutants might produce such effects.

Thus the benefits deriving from the health research will be realized in terms of reducing uncertainties regarding the nature and magnitude of adverse health effects among the public and the synfuels-industry work force. The value of this reduced uncertainty, though difficult to quantify in economic terms, can nevertheless be appreciated when one merely considers the consequences of occupational exposures to cancer-causing organic chemicals in industries that were in operation before risks were clearly understood and before hazards could be adequately mitigated. For example, workers exposed to airborne emissions in coke-oven plants have shown a greater potential to develop lung cancer than the general population.

Risk analysis is developing as one possible approach to the systematic use of information to estimate potential health and environmental consequences of man's activities. Thus risk analysis, also, has become an integral part of the program of the Office of Health and Environmental Research, and this activity has also made its contribution to knowledge of synfuels effects. As an example, it has long been recognized that a portion of the particles in the air we breathe comes from coal combustion, the use of petroleum fuels in diesel and gasoline engines, and, potentially, from synfuels processing. The risk-analysis activity made use of data on the characteristics of these particles and their dispersion and transport in air to estimate the health consequences of their uptake and retention in people. Such estimates have proved particularly useful where particles pose the principal concern, as in the exhausts of automotive diesels. A related activity studied the possible consequences of substituting coal for oil as utility fuel, and here other pollutants such as sulfates (which themselves can be particles) become dominant concerns. Eventually, what began as more limited contributions (i.e., developing methods for estimating the health effects of particles and sulfates) found application in a wide range of analyses of the risks of other pollutants, including many encountered in synfuels.

Responding to Hazardous Events Events in recent years, such as the reentry and distribution of nuclear space debris within the Earth's atmosphere and the atmospheric testing of nuclear weapons by some foreign powers, have given rise to questions regarding our ability to evaluate and to react to such possible emergencies and their consequences. Two complementary systems that provide such a capability were developed under the OHER research program and are operational today. One, the Atmospheric Release Advisory Capability (ARAC), can predict the travel and dispersion of hazardous substances released into the atmosphere, is easily activated, and can provide results to users via direct communications. Initiated in the 1960's because of concern about fallout from atmospheric nuclear-weapons testing, the system has been expanded to provide 24-hour coverage for federal and state emergency-response support in a range of such possible situations as nuclear-weapons tests and accidents, spills of hazardous chemicals, and nuclear-power-plant releases.

The second system is designed specifically for forecasting fallout from nuclear-weapons tests and to alert federal agencies having responsibilities for monitoring, for contaminant collection and analysis, and for informing the public. Forecasting the consequences of the test is accomplished by providing relevant input to ARAC (described previously).

Detection and Measurement of Human Health Effects

Program responsibilities have required support for developing instruments and techniques to detect energy-related human health effects. These developments have found specialized use in hospitals and clinical laboratories, in research laboratories, and in government and industrial applications.

Cell Sorting Two instruments of this kind in use today in hospitals and clinics are the *flow cytometer* and the *centrifugal fast analyzer*. The flow cytometer was developed in 1965 to distinguish cells damaged by radiation from normal cells. Since then, the methods used for cell sorting and their applications have continued to increase. Today the flow cytometer is used routinely for complete blood counts (its greatest single application), for detecting cancer and monitoring its treatment, and for detecting genetic abnormalities. The centrifugal fast analyzer also had its beginnings in the search for tools to measure radiation effects in humans. The analyzer, which exploits advances made in centrifuge technology in the 1960's, can handle simultaneously a large number of blood samples for automated analysis. It is used principally to run blood-chemistry tests for diagnostic purposes and accounts for about 10 percent of all such tests conducted in hospitals and commercial laboratories in the United States each year. About 10,000 units are in worldwide use.

A Fast Test for Cancer-Causing Chemicals *Short-term cell bioassays* were developed largely for research purposes. These tests are intended as quicker and cheaper screens prior to more costly animal tests in screening for cancer-producing or cell-altering characteristics. A number of tests are included within the meaning of short-term cell bioassays. One of the most widely used of these is the Ames Test developed in this program. In this test, chemicals

are checked to see if they provide mutations in a specific line of bacteria. If they do, additional bioassay tests with cultured human or animal cells may then be employed. Short-term cell bioassays require only a fraction of the cost (an estimated $35 million is spent annually) and time of comparable screening by animal studies, and therefore many more compounds can be screened than was possible earlier.

Analyzing Complex Mixtures for Toxic Agents Industries and government have responsibilities requiring a range of instruments and techniques to protect human health. Two instruments, in particular, have been useful as scanners and detectors of elements in complex mixtures found in the workplace and in the environment. One of these developments is based upon an instrument in use since the 1930's, the crystal X-ray spectrometer, which identified elements in an irradiated sample by the characteristics of the reflected X radiation. In today's instrument, the crystal has been replaced by a semiconductor detector that can distinguish among many elements by producing currents which are unique to each irradiated element and which can be processed and identified automatically. Approximately 8300 semiconductor X-ray spectrometers are now in use. The average annual savings to users of these spectrometers, in terms of reduced analytical costs as compared with other techniques of elemental analysis, is estimated to be at least $43 million. This figure is conservative since it is based on savings to only 1300 commercial users, who are in a better position than other users to estimate tangible benefits.

The other highly significant development in instrumentation, also a spectrometer, was designed specifically to identify radioactive materials. The scintillation spectrometer, commonly used for this purpose until 1965, could not distinguish well enough between radioactive elements with emissions of similar energies. Once again, the development of new crystal detectors led to a more capable instrument, now called the *high-resolution gamma-ray spectrometer*. Today it is used widely in nuclear power plants and laboratories and by state and local agencies to monitor the environment as well as in many research applications. Based on the value of rapid analysis as compared with slower alternatives, the benefit to nuclear plant operation alone is estimated to be $20 million annually.

Industrial Hygiene Monitoring The research program has also supported the development of instruments to detect and monitor toxic chemical substances. Specifically, it has supported the compilation of information relevant to instrumentation for all environmental monitoring applications. This survey has been in use as a standard for several years and will soon be issued by a private publisher. In addition, the program has supported the development of monitoring instruments specific to three important toxic chemicals which were formerly unavailable.

Predicting Pollution Pathways in the Atmosphere Finally, the means by which pollutants are carried and dispersed in the atmosphere have been traditionally the subject of intense study in the research program. Understanding and predicting pollutant transport are important because transport is a principal means by which health effects might be produced in the public by an emerging technology. The research program pioneered the mathematical modeling, or prediction, of pollutant behavior in the atmosphere because of the early responsibility for understanding the possible effects of radioactive contamination. But the validity of models and predictions must be tested, and in this area also the program has supported the development of the necessary tools for verification. One of these developments has been the use of nonradioactive, nontoxic, inexpensive tracers (related to the refrigerant used in home air conditioning). These tracers are injected into the air at designated locations at known release rates, and their concentrations are later measured at other locations to determine the dispersive effects of meteorological factors, terrain, conditions of release, etc. Although gas tracers have provided valuable information of this kind, it is also known that pollutant gases often interact with minute particle clouds (aerosols) from which they may be deposited on the ground or become resuspended in air. Pollutants themselves may even originate as aerosols. Thus the program has also supported instruments to monitor aerosol behavior. The major benefit of this research has been a sounder understanding of the relationships between pollutant releases and pollutant concentrations in the human environment, information that is essential to regulation of pollutants in the general interest and for sound industrial planning.

Identification and Evaluation of Environmental Effects

Effects of emerging technologies on the environment, as well as on human health, are a prime concern of the research program. Among the major environmental issues today are the responsible uses of land and water resources. Pertinent to land use, fundamental research in soil science and plant ecology is aimed at developing an understanding of the processes that lead to changes in soils and plants.

Riverine Ecology In the area of water resources, fundamental research has been of value to regulatory bodies in determining to what extent rivers and other inland waters can be used for industrial cooling. In one instance, the issue was whether the impact of several operating power plants on the Hudson River would seriously damage important East Coast fish populations that inhabit the lower part of the river. The research program on riverine ecology

provided sufficient information for a reasonable estimate of this impact. These results provided a scientific basis for compromise between the Environmental Protection Agency, interveners in the proceedings, and the utilities involved.

Ecology of the Continental Shelf The continental shelf is critical to humans. Its fertile coastal waters, which account for less than 10 percent of the total ocean area, produce 40 percent of our seafood. The research performed by a number of laboratories and universities working in specific sectors of the shelf, is well coordinated with work conducted under the auspices of other federal agencies with related responsibilities. Some fundamental mechanisms by which pollutants, as well as nutrients, enter the food chain are being established. The research program has also included studies of mechanisms by which pollutants are carried across the continental shelf into the deep ocean and of their effects on living systems. Potential benefits include a better understanding of the effects of sea disposal of municipal and other wastes, possible effects of such offshore operations as oil development, and the consequences of oil spills and of other accidental releases of chemicals in coastal areas.

Tracing Pathways of Nuclear Wastes in the Life Cycle Environmental studies in areas other than land and water use have also yielded information on the cycling of pollutants from human activities through the environment and back to humans or to other biological organisms. Several defense-related facilities process radioactive materials in the *transuranic* category (elements heavier than uranium), which are potentially hazardous to humans. Thus laboratories at the Savannah River Plant in South Carolina have for many years studied the possible uptake of these materials in the environment and the consequent potential for human ingestion. Thus far, measurements of minute concentrations of transuranics in the air and in crops grown in soils near these defense facilities indicate that the dose to humans is minuscule compared with that which results from naturally radioactive materials. These results have been compiled and form the basis for other determinations that may be made in the future regarding civilian and military applications of nuclear technology involving transuranic elements.

A similar situation arose with the question of the fate of other radioactive materials released in fallout from nuclear-weapons tests. Tracer research, undertaken early in the period when such atmospheric tests were conducted, led to the understanding that some elements, when transmitted up a food chain, concentrate at various levels. They can pass from one level to the next only through feeding (e.g., uptake of iodine-131 in forage eaten by dairy cows, whose milk would then be consumed by humans). This research has proved extremely valuable to the development of a better understanding of the functions of biological systems, as well as to assessments of the environmental impacts of proposed nuclear facilities.

Plant Metabolism A particularly useful application of radioisotope tracers has permitted a complete mapping of the pathways of carbon in the photosynthesis process. With carbon-14 as the tracer, the process from the initial fixation of carbon dioxide from the atmosphere has been followed through to the production of glucose by green plants. This understanding of the detailed biochemistry of photosynthesis laid the groundwork for new areas of investigation, such as the acceleration of plant growth and other forms of metabolic control. Another benefit provided by carbon-14 as a tracer is detailed information on intermediate chemical products and enzymes associated with both plant and animal metabolism. A spectrum of genetic engineering techniques and developments is therefore now possible.

Land Reclamation Field research studies were undertaken at mining sites in three different environments: (1) a strip mine in a grassland area of Wyoming; (2) an arid area of New Mexico; and (3) in fertile Illinois farmland. The strip-mine studies have demonstrated less expensive and more effective use of topsoil in land reclamation. The potential savings through adoption of the technique in western mine areas alone could be $600 million over the next 20 years. The studies in New Mexico showed that several kinds of hybrid plants that are highly drought tolerant could be well adapted to the reclamation of arid areas. The research in Illinois focused on techniques for returning mined, prime farmland to production. In Illinois, as in Wyoming, less expensive methods of land reclamation were found to be at least as effective as those now in practice.

Detection and Measurement of Environmental Effects

Detecting Change Over the Ages Evaluation of the effects of pollutants on the environment, as on human health, requires the development of specialized measuring techniques. Just as a radioisotope can tell of a patient's condition and tracers can give clues to the paths taken by pollutants in the atmosphere, so, too, can a similar technique give insight into geological events of long standing. Previously unanswerable questions can now be addressed. For example: How fast is land eroding? How fast are glaciers building? How old is groundwater? How fast is it replenished?

The technique that makes it possible to answer these questions uses *isotope ratios* and evolved from basic research begun in the 1950's to an understanding of long-term changes in environmental processes. Isotopes are nothing more than differing nuclear forms of the same element and therefore have the same chemical behavior, but they can be

observed individually because of their unique nuclear properties. As noted earlier, the role of carbon dioxide in photosynthesis (a chemical process) can be observed by injecting a known quantity of carbon-14 as carbon dioxide and tracing its path. This is made possible by measuring the radioactivity of carbon-14, which takes part in the process in the same way as its natural stable sister isotope, carbon-12. The measurement of radioactivity is also a measure of the quantity of carbon-14 present at any stage of the process; but the *ratio* of carbon-12 to carbon-14 tells us the *total* amount of carbon involved.

After its use in radiocarbon tracing in the early 1950's, the technique of isotope ratios found many applications in environmental geology. In quick succession it yielded histories of lake and marine sediments, knowledge of the movements of the atmosphere and underground waters, information on biological processes—in short, vital information on the paths taken by pollutants throughout the environment, the rates at which they are purged, and the extent to which they can accumulate to pose risks.

Nuclear Medicine

OBJECTIVE: Develop to Its Highest Potential the Application of Nuclear Science to the Diagnosis and Treatment of Human Disease.

The phenomenon of radiation was considered by early investigators to be an opportunity for improved health care as well as a health risk. What was the basis for their optimism? Simply that a unique tool could be made available in forms convenient for use by the medical profession for diagnosis as well as the treatment of human diseases. Through nuclear medicine, it would be possible to monitor body function, to isolate the causes and extent of disease, and to subject these to a range of treatments never before possible.

Techniques That Aid in Diagnosis

Heart Disease There are two major techniques for diagnosing whether patients with symptoms of coronary artery disease in fact have such disease. One involves the injection of opaque dye into an artery near the heart, after which the motion of the dye is followed by fluoroscopy. This technique, called cardiac catheterization, is painful and expensive and carries risks. The other technique, developed in the nuclear medicine program, involves injection of the radioisotope thallium-201 into the bloodstream and subsequent detection of the uptake of this tracer in cellular tissue. Reduced uptake of thallium-201 in a region indicates either reduced blood flow or damage to cells, or both. Thus the technique can detect damage to the cells of the heart and reduced blood flow to the heart. The technique is relatively inexpensive, less invasive, and low risk. Although it does not exclude the use of cardiac catheterization (which is usually required prior to surgery, once the presence of disease is confirmed), the thallium-201 scan is in wide use as a screening test, often obviating the need for catheterization. For the 370,000 patients who undergo the scan annually and avoid the necessity for more expensive catheterization, this has meant a savings of $78 million per year in medical expenses.

Diagnostic Scanning The need for a versatile scanning technique, adaptive to a range of diagnostic applications, was fulfilled through the use of the radioisotope technetium-99*m* for imaging with the scintillation camera. The "daughter" from the quick decay of this radioisotope was found to produce low-energy electrons just sufficient for satisfactory tissue penetration and detection by the camera. With this approach it is possible to determine the amount and rate of blood flow to an area, whether an organ has normal or impaired functions, and the presence or absence of tumors, particularly in the brain, liver, and bone. At least 6 million technetium-99*m* studies are performed annually, representing approximately 80 percent of all nuclear medicine imaging procedures. Industry is currently producing technetium-99*m* with a sales volume totaling $26 million per year.

Hodgkin's Disease The radioisotope gallium-67 has been used in a number of applications in nuclear medicine because it concentrates in tumors and abscesses and because of the efficient detectability of its gamma-ray emissions. Gallium-67 scanning is particularly useful in the diagnosis of Hodgkin's disease in a procedure that also permits discrimination between the various stages of this disease. The ability to discriminate is valuable because treatment is specific for each stage of the disease. The benefit of the scan to patients who have not yet reached the most severe stage of the disease, in terms of avoiding unnecessary medical expenses and losing productive time alone, is estimated to be $10 million annually. In all applications, more than 250,000 gallium-67 scans are performed annually at a cost of $5 million for the radiopharmaceutical alone.

Instruments That Aid in Diagnosis

The Scintillation Camera The scintillation camera, named the "Anger Camera" for its inventor, was de-

vised to obtain successive images of the distribution of a radioactive tracer within the body after intravenous injection of the tracer. Thus it is used widely in conjunction with the diagnostic tracer techniques described earlier (thallium-201 and technetium-99*m*), representing 80 percent of all *in vivo* studies in nuclear medicine. About one in four patients in American hospitals undergoes an examination with the scintillation camera as part of the process of medical diagnosis. Almost 7000 cameras are now being used in hospitals of all sizes in the United States, and 3000 of these are used in conjunction with computers to enhance the images produced.

Scanning Instruments The familiar CAT Scan (Computer Assisted Tomography Scanning) is a vital tool in medical diagnosis, yielding three-dimensional views that reveal body structure in striking detail. However, because CAT Scans cannot depict the active functioning of body organs, there was a further need for a device that could provide such views of regional physiological processes, such as blood flow and metabolism. This led to the development of the PET (Positron Emission Tomography) scan and the use of short-lived radioisotopes of elements that occur naturally in the body (e.g., oxygen, nitrogen, and carbon). Once these radioisotopes are injected and become distributed, their positron emissions are attracted to electrons associated with the normal matter in the body. Both particles are thus annihilated, and a new form of energy is emitted which can be detected by the PET scanner. This information is processed by computer to reconstruct images of the internal distribution and movement of the radioisotope and thus the functioning of the organ of interest. Several companies now manufacture the PET scanner at costs of about $1 million per unit. This instrument is considered to be enormously valuable in diagnosing and understanding diseases of the brain (e.g., cancer, mental diseases, epilepsy) and of the heart and lungs.

Instrument Standardization Nuclear instruments, including those used in nuclear medicine, are produced by many manufacturers and at one time were not compatible electrically or mechanically. In any new situation it was often necessary either to forego the use of instruments on hand or to replace them with compatible units at considerable cost. Under the nuclear medicine program, a modular nuclear instrument system was developed to provide mechanical and electrical power supply interchangeability. Other compatible modules were designed to feed signals from these instruments to computers and other processors and associated software. These concepts were adopted by standards-setting institutions and manufacturers and have been promulgated worldwide. Annual U.S. sales of the modular and automated systems amount to $23 million and $17 million, respectively, and represent 50 to 60 percent of the world market.

Treatment

Hyperthyroidism Hyperthyroidism, characterized by excessive levels of circulating thyroid hormones, can be marked by a variety of clinical conditions, including increased metabolic rate, enlargement of the thyroid gland, rapid heart rate, and high blood pressure. The three major treatments for this condition (surgery, drugs, or iodine-131 therapy) focus on destroying the abnormal thyroid tissue that is producing the excess hormone. Surgery to remove the thyroid gland is painful and expensive and carries risks. The use of drugs requires long-term treatment, incurs possible side effects, and may eventually end in surgery. However, it was found in the early 1940's that the iodine-131 radioisotope concentrates in the thyroid gland, and a means to destroy overactive tissue through short-range particle emissions was thus provided. The early discovery of this treatment and its selectivity are evident from the fact that, from the mid-1940's to the late 1960's, iodine-131 was the principal radioisotope used in nuclear medicine. For almost 50,000 persons each year in the United States who undergo iodine-131 treatment in place of surgery, the annual savings in terms of productive time and lower medical costs have been computed to be $280 million.

Parkinson's Disease Parkinson's disease, a debilitating neurological disease, afflicts close to one million persons, with 50,000 new cases per year. In two-thirds of the cases, the onset of symptoms occurs between the ages of 50 and 70 and becomes progressively worse. In the early 1950's, several radioisotopes, particularly manganese-56, were used to investigate a possible link between trace metals and this disease. Although no conclusive connection could be made between the disease and manganese poisoning, several new areas of research evolved from these studies. Eventually, it was found that there is a deficiency of an amino acid, dopamine, in the brains of persons suffering from Parkinson's disease and that this amino acid could be synthesized internally after intravenous injection of a related compound, L-dopa. The treatment does not cure the disease but can mitigate the severity of its progression. It produces initial improvement in 50 to 75 percent of the cases, slows the rate of advance of the disease, and decreases the mortality rate. Thus the benefits of this treatment can be measured in terms of improved quality of life (i.e., increased years of work and independence and a decreased or postponed period of incapacity) with an average increase of 2.5 person-years of active or productive time per person afflicted. Based on 50,000 new cases per year in the United States, this translates to a gain of approximately 125,000 person-years of active life annually.

The Future

This brief account of selected accomplishments over the 40-year program of energy-related health and environmental research only partially illustrates its role in fulfilling an important national need. Use of this style of presentation makes it difficult to convey the program's most important characteristics: an evolutionary, integrated, and multidisciplinary research commitment; a synergism between fundamental science and applied problem solving; and an inevitable share of scientific setbacks as well as achievements. Thus the accomplishments in reality represent a continuum of scientific development—from the basic unraveling of bioenvironmental processes and the coupling of seemingly disparate facts to their application to specific problems.

These program characteristics, in turn, lend a distinct characteristic to the research itself: it is built continually upon an established base of knowledge, the rewards becoming increasingly apparent far downstream of the initial thought and investment. Thus, to a large extent, the program's future accomplishments are already embedded in its studies of the past and the present.

As a part of the evolving national energy mission, a responsive research program has developed the expertise and facilities required for its newer roles. The evolution continues, centered around a long-term commitment to fundamental and basic research, toward addressing problems and issues of a high-risk nature with an anticipatory rather than a regulatory approach. Of particular importance to the future is the fact that the program's multidisciplinary talent and capabilities in unique, dedicated facilities constitute a valuable national resource.

The research program is therefore as well equipped to meet future challenges as it was to meet past challenges. As our energy mission continues to evolve, with changing patterns of energy demand and the accompanying development of

responsive new sources, it is reasonable to expect research contributions to assure safety, acceptability, and compatibility with the national goal. On this point it is significant that atmospheric science and the health effects of chemical exposures (two of the three elements of the energy-related *source–transport–effect* triad) were among the seven research areas recently identified by the President's Science Advisor as likely to return the highest future scientific dividends as a result of incremental federal investments.

The promise for the future therefore lies within the program's traditionally interactive and interdisciplinary approach to complex problems. New biophysical and chemical tools and techniques in biomedical and environmental research now make it possible to attempt unprecedented studies on cells, molecules, and processes relevant to the "tried." These technical advances, applied to basic studies, will continue to contribute to answering energy-related questions, as well as to increasing knowledge about *causes* and *effects* in biological systems. And, as in the search for radiation repair mechanisms which led to discoveries of DNA behavior and important theories of the nature of human disease and its treatment, the program's research will continue to lead in making fundamental and practical contributions in reducing uncertainties on the health and environmental aspects of emerging energy technologies.

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Department of Energy
Washington, D.C. 20585

AUG 2 1 1986

Honorable John Glenn
Ranking Minority Member
Subcommittee on Energy, Nuclear
Proliferation, and Government Processes
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Glenn:

At your request, the General Accounting Office (GAO) performed a review which resulted in GAO's report RCED-86-175 entitled "Safety Analysis Reviews for DOE's Defense Facilities Can Be Improved" containing recommendations for the Department of Energy (DOE). As required by 31 U.S.C. 720, DOE has provided comments on the report to the House Committee on Government Operations, the Senate Committee on Governmental Affairs, and the House and Senate Committees on Appropriations. Because of your interest in the report, a copy of DOE's response is enclosed for your information.

DOE would be pleased to provide any additional information that is desired in this matter.

Sincerely,

Martha O. Hesse
Assistant Secretary
Management and Administration

Enclosure

cc w/enclosure:
Honorable Thad Cochran
Chairman, Subcommittee on Energy, Nuclear
Proliferation, and Government Processes
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510

DOE COMMENTS ON GAO REPORT
"SAFETY ANALYSIS REVIEWS FOR DOE'S DEFENSE FACILITIES CAN BE IMPROVED"
RCED-86-175

Following are the General Accounting Office (GAO) recommendations to the Secretary of Energy and the Department of Energy's (DOE) related comments.

GAO Recommendation 1

"We recommend that the Secretary of Energy

- o Complete and approve SARs for all high hazard facilities in a timely fashion."

DOE Comment

DOE concurs and will take action to assure compliance with this recommendation. All operating high hazard nuclear facilities have had a continuous history of safety assessments from the time of their original construction; however, some do not have a formal Safety Analysis Report (SAR) which has been formally approved by DOE. Even though controls deemed necessary for safe operation are specified by DOE approved Operational Safety Requirements, all SARs for existing high hazard facilities are scheduled to be reviewed and approved by the end of FY 1987. The Office of Environment, Safety and Health will track them to assure timeliness of completion.

GAO Recommendation 2

"We recommend that the Secretary of Energy

- o Require that SARs include a detailed comparison of the plant against current DOE design criteria, highlighting and explaining any deviations."

DOE Comment

DOE Orders require that safety analyses be based upon current technical criteria. Documentation of this is presented in the facility's Conceptual Design Report and/or in the applicable Design Criteria Document. These documents are used to systematically identify safety areas that warrant additional consideration in an SAR. DOE will require that such evaluations be incorporated into the SAR either through revisions of appropriate sections of the report or as an appendix. For existing SARs, this evaluation would be added at the time of the next normal update. Also, as part of the Secretary's initiatives, the Office of Environment, Safety and Health, which is independent of any operating responsibility for nuclear facilities, will be reviewing the SARs and supporting documents for major nuclear facilities. These reviews will include a comparison of the design against current DOE criteria. This will provide additional assurance that this DOE requirement is met and is appropriately documented in a consistent fashion. The above actions will ensure that the GAO recommendation is met.

GAO Recommendation 3

"We recommend that the Secretary of Energy

- o Develop more consistent requirements to be followed in preparing SARs, outlining appropriate methodologies and assumptions to be used in analyzing accidents and their consequences."

DOE Comment

One of the major objectives of the Secretary's new initiatives is to improve an understanding of and consistency in the implementation of the Department's overall Environment, Safety and Health program. With regard to the safety analysis and review process, this will be accomplished in two ways: first, updated and improved guidance will be provided; and second, the independent Headquarters Office of Environment, Safety and Health will review SARs. Additional guidance is being provided by this office through the recently published "Guide to Radiological Accident Considerations for Siting and Design of DOE Nonreactor Nuclear Facilities," January 1986, the soon to be finalized updates of the "Nonreactor Nuclear Facilities: Standards and Criteria Guide," the "Nuclear Air Cleaning Handbook," and the development of more detailed guidance for analyzing natural phenomena hazards, which is scheduled to be completed in 1987. This guidance will be incorporated into the DOE Orders, as appropriate. DOE will also develop guidance in the areas of SAR reviews and Operational Safety Requirements. Also, the Departmental requirements for new nonreactor nuclear facilities SARs have recently been updated to formally require consideration of appropriate NRC standard format and content guidelines. For DOE nuclear reactors this requirement has been in place for some time. The safety analysis and review process has been significantly enhanced by requiring concurrence by the Assistant Secretary for Environment, Safety and Health on the construction and startup authorizations of all new reactor and high hazard nonreactor nuclear facilities, and selected moderate hazard nonreactor nuclear facilities. Review and concurrence on significant modifications to existing facilities will also be required. In addition, about one-third of the approximately 120 high and moderate hazard operating facilities will be reviewed by the Office of Environment, Safety and Health. A sampling plan is being developed to select the SARs for review. The results of the first group of SAR reviews will determine if more than the pre-selected one-third need to be reviewed. These reviews will further assure that DOE facilities are consistently evaluated and compared against DOE design criteria and assure that uniform approaches and assumptions are utilized in the accident analyses presented in the reports.

GAO Recommendation 4

"We recommend that the Secretary of Energy

- o Establish an arrangement with an outside independent organization to review those SARs for the most hazardous facilities. This could be accomplished either by establishing a working arrangement with NRC or an independent review panel."

DOE Comment

Pursuant to Secretary Herrington's 1985 initiatives in environment and safety, an organization which is independent of any operating responsibility for DOE's production facilities, has been established to overview the Department's activities. That organization is the Office of the Assistant Secretary for Environment, Safety, and Health.

As part of the Secretary's initiatives, this independent organization will review the SARs for new high hazard and selected moderate hazard nuclear facilities within the DOE complex. Concurrence on the acceptability of these analyses by this organization will be required on the construction and startup authorizations. Also, as described above, independent reviews of select SARs for existing operating nuclear facilities are planned. With respect to the suggestion for a non-DOE review group, it must be noted that DOE has a variety of missions including research, development, and production. This diversity of facilities, operations, and functions has required the development and institutionalization of a dedicated cadre of scientists, engineers and operating personnel with a unique and internationally known capability to oversee and operate the DOE complex of facilities. This same expertise and capability are frequently called upon to provide technical guidance and first hand experience to support national and international bodies in developing safety rules and standards. Therefore, to establish an additional level of oversight, over and above that already existing under the guidance of the Assistant Secretary for Environment, Safety, and Health, would not provide any additional assurance of the safe operation of DOE facilities and would not be warranted in view of the expertise that already resides in the Department.

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